(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 908 156 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
14.04.1999 Bulletin 1999/15

(51) Int Cl.[6]: **A61B 17/39**

(21) Application number: **98204115.4**

(22) Date of filing: **11.08.1995**

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **12.08.1994 US 290031**

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
95928379.7 / 0 777 445

(71) Applicant: **Rita Medical Systems, Inc.**
Mountain View, CA 94043 (US)

(72) Inventors:
- **Edwards, Stuart D.**
Portola Valley, California 94028 (US)
- **Lax, Ronald G.**
300 Palm City, Florida 34990 (US)
- **Sharkey, Hugh**
Redwood Shores, CA 94065 (US)

(74) Representative: **Harris, Ian Richard et al**
D. Young & Co.,
21 New Fetter Lane
London EC4A 1DA (GB)

Remarks:
This application was filed on 04 - 12 - 1998 as a divisional application to the application mentioned under INID code 62.

(54) Multiple electrode ablation apparatus

(57) A tissue ablation apparatus includes a delivery catheter with distal and proximal ends. A handle is attached to the proximal end of the delivery catheter. At least partially positioned in the delivery catheter is an electrode deployment device. The electrode deployment device includes a plurality of retractable electrodes. Each electrode has a non-deployed state when it is positioned in the delivery catheter. Additionally, each electrode has a distended deployed state when it is advanced out of the delivery catheter distal end. The deployed electrodes define an ablation volume. Each deployed electrode has a first section with a first radius of curvature. The first section is located near the distal end of the delivery catheter. A second section of the deployed electrode extends beyond the first section, and has a second radius of curvature, or a substantially linear geometry.

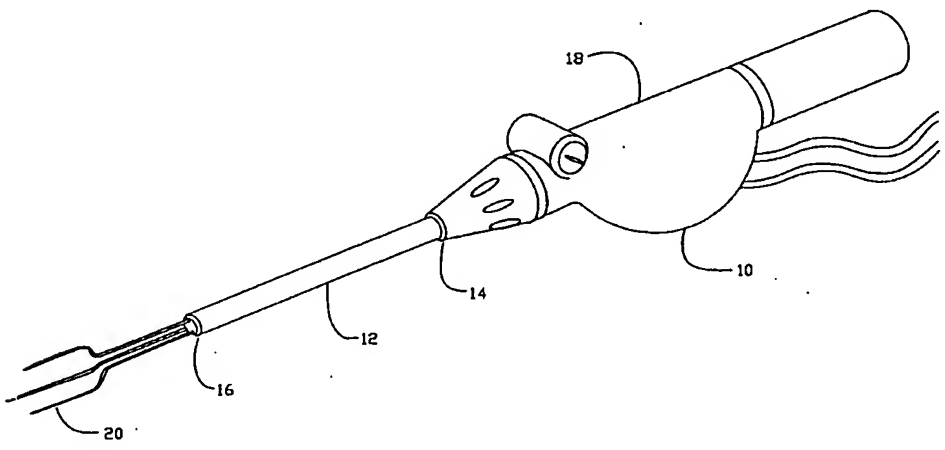


FIG. 1

EP 0 908 156 A1

Description

[0001] This invention relates generally to an apparatus for the treatment and ablation of body masses, such as tumors, and more particularly, to a retractable multiple needle electrode apparatus that surrounds an exterior of a tumor with a plurality of needle electrodes and defines an ablative volume.

[0002] Current open procedures for treatment of tumors are extremely disruptive and cause a great deal of damage to healthy tissue. During the surgical procedure, the physician must exercise care in not cutting the tumor in a manor that creates seeding of the tumor, resulting in metastasis. In recent years development of products has been directed with an emphasis on minimizing the traumatic nature of traditional surgical procedures.

[0003] There has been a relatively significant amount of activity in the area of hyperthermia as a tool for treatment of tumors. It is known that elevating the temperature of tumors is helpful in the treatment and management of cancerous tissues. The mechanisms of selective cancer cell eradication by hyperthermia are not completely understood. However, four cellular effects of hyperthermia on cancerous tissue have been proposed, (i) changes in cell or nuclear membrane permeability or fluidity, (ii) cytoplasmic lysomal disintegration, causing release of digestive enzymes, (iii) protein thermal damage affecting cell respiration and the synthesis of DNA or RNA and (iv) potential excitation of immunologic systems. Treatment methods for applying heat to tumors include the use of direct contact radio-frequency (RF) applicators, microwave radiation, inductively coupled RF fields, ultrasound, and a variety of simple thermal conduction techniques.

[0004] Among the problems associated with all of these procedures is the requirement that highly localized heat be produced at depths of several centimeters beneath the surface of the body. Certain techniques have been developed with microwave radiation and ultrasound to focus energy at various desired depths. RF applications may be used at depth during surgery. However, the extent of localization is generally poor, with the result that healthy tissue may be harmed.

[0005] Induction heating gives rise to poor localization of the incident energy as well. Although induction heating may be achieved by placing an antenna on the surface of the body, superficial eddy currents are generated in the immediate vicinity of the antenna. When it is driven using RF current unwanted surface heating occurs diminishing heating to the underlying tissue.

[0006] Thus, non-invasive procedures for providing heat to internal tumors have had difficulties in achieving substantial specific and selective treatment.

[0007] Hyperthermia, which can be produced from an RF or microwave source, applies heat to tissue but does not exceed 45 degrees C so that normal cells survive. In thermotherapy, heat energy of greater than 45 degrees C is applied, resulting in histological damage, desiccation and the denaturization of proteins. Hyperthermia has been applied more recently for therapy of malignant tumors. In hyperthermia, it is desirable to induce a state of hyperthermia that is localized by interstitial current heating to a specific area while concurrently insuring minimum thermal damage to healthy surrounding tissue. Often, the tumor is located subcutaneously and addressing the tumor requires either surgery, endoscopic procedures or external radiation. It is difficult to externally induce hyperthermia in deep body tissue because current density is diluted due to its absorption by healthy tissue. Additionally, a portion of the RF energy is reflected at the muscle/fat and bone interfaces which adds to the problem of depositing a known quantity of energy directly on a small tumor.

[0008] Attempts to use interstitial local hyperthermia have not proven to be very successful. Results have often produced nonuniform temperatures throughout the tumor. It is believed that tumor mass reduction by hyperthermia is related the thermal dose. Thermal dose is the minimum effective temperature applied throughout the tumor mass for a defined period of time. Because blood flow is the major mechanism of heat loss for tumors being heated, and blood flow varies throughout the tumor, more even heating of tumor tissue is needed to ensure more effective treatment.

[0009] The same is true for ablation of the tumor itself through the use of RF energy. Different methods have been utilized for the RF ablation of masses such as tumors. Instead of heating the tumor it is ablated through the application of energy. This process has been difficult to achieve due to a variety of factors including, (i) positioning of the RF ablation electrodes to effectively ablate all of the mass, (ii) introduction of the RF ablation electrodes to the tumor site and (iii) controlled delivery and monitoring of RF energy to achieve successful ablation without damage to non-tumor tissue.

[0010] There have been a number of different treatment methods and devices for minimally invasively treating tumors. One such example is an endoscope that produces RF hyperthermia in tumors, as disclosed in U.S. Patent No. 4,920,978. A microwave endoscope device is described in U.S. Patent No. 4,409,993. In U. S. Patent No. 4,920,978, an endoscope for RF hyperthermia is disclosed.

[0011] In U.S. Patent No. 4,763,671, a minimally invasive procedure utilizes two catheters that are inserted interstitially into the tumor. The catheters are placed within the tumor volume and each is connect to a high frequency power source.

[0012] In U.S. Patent No. 4,565,200, an electrode system is described in which a single entrance tract cannula is used to introduce an electrode into a selected body site.

[0013] The medical probe device described in WO-A-94-04220 comprises a catheter for insertion in an orifice in a body and has a stylet guide housing with one or

more stylet ports in a side wall thereof and a stylet guide for directing a flexible stylet outwards through a stylet port and through intervening tissue at a preselected adjustable angle to a target tissue. The catheter assembly includes a stylet guide lumen communicating with the stylet port and a stylet positioned in the stylet guide lumen for longitudinal movement from the port through an intervening tissue to a target tissue. The stylet can be an electrical conductor enclosed within a non-conductive layer, the electrical conductor being a radio frequency electrode.

[0014] German Gebrauchsmuster, DE-U-8909492 describes an interocular phacofragmentation device having a pair of gripping arms insertable through a cornea. Through the action of high-frequency current via the gripper arms, denaturation of proteins in the lens nucleus is achieved. The gripper arms also enable the nucleus of the lens, which is too hard for ultrasonic fragmentation, to be crushed during rearward movement of those arms. The gripper arms are extended from a guide sleeve which is held adjacent the exterior surface of the cornea.

[0015] According to page 1 of German published patent application DE-A-2,124,684, this document describes an insertion electrode for biomedical uses which enables larger objects such as electrodes or massaging heads to be inserted into body tissue or body cavities. According to page 3, the electrodes can be formed from, for example, wires, conductive gasses and conductive fluids. According to page 4, the wires can be formed as tubes so that the fluids and gasses can be passed therethrough. The only uses of the electrodes mentioned on page 3 are as antennae, heating for shortwave therapy, and cauterization, as well as operation instruments, for ionophoresis, or cascade ionophoresis, for the destruction of tumours and finally for mechanical vibrators for loosening of tissue and the destruction of tumours.

[0016] To be an effective treatment device for a tumour, electrodes must be properly positioned relative to the tumour. After the electrodes are positioned, it is then desirable to have controlled application and deposition of RF energy to ablate the tumour. This reduces destruction of healthy tissue.

[0017] Accordingly an aim of the invention is to provide an RF tissue ablation apparatus which ablates a desired tissue site, such as a tumour, in a minimally invasive manner. In accordance with the invention, there is provided an ablation apparatus, comprising: an introducer having a proximal end, means for holding the introducer, a lumen and a distal end sufficiently sharp to penetrate tissue; an energy delivery device including a first RF electrode with a tissue piercing distal portion and a second RF electrode with a tissue piercing distal portion, the first and second RF electrodes being positionable in the introducer as the introducer is advanced through tissue and deployable with curvature from the introducer at a selected tissue site in a lateral direction away from the periphery of the introducer; and an RF electrode advancement member coupled to the first and second RF electrodes and configured to advance the first and second RF electrodes through tissue.

[0018] Thus an embodiment of the invention can provide an RF tissue ablation apparatus which includes a selectable plurality of retractable electrodes which are advanced from a delivery catheter to define an ablation volume. The delivery catheter provides an elongate arrangement insertable into body tissue for permitting the insertion of electrodes to a desired position within a body.

[0019] An embodiment of the invention can provide an RF tissue ablation apparatus which includes a plurality of electrodes that are retractable to and from a delivery catheter. The electrodes are at least partially positioned in the delivery catheter in a non-deployed state, and become distended in a deployed state when advanced out a distal end of the delivery catheter, defining the ablation volume.

[0020] An embodiment of the invention can provide an RF tissue ablation apparatus with deployed electrodes having a first section with a first radius of curvature, and a second section, that extends beyond the first section, having a second radius of curvature or a substantially linear geometry.

[0021] An embodiment of the invention can also provide an RF tissue ablation apparatus with deployed electrodes with two or more radii of curvature, for example with at least one radii of curvature in two or more planes.

[0022] In an embodiment of the invention an RF tissue ablation apparatus with at least one deployed electrodes can have one curved section located near a distal end of the delivery catheter, and a non-curved section extending beyond the curved section of the deployed electrode.

[0023] Alternatively, or in addition, the tissue ablation apparatus can include a deployed electrode with at least one curved section located near a distal end of a delivery catheter, and a non-curved section which extends beyond the curved section of the deployed electrode.

[0024] In a particular embodiment, a tissue ablation apparatus includes a delivery catheter, with distal and proximal ends. A handle is attached to the proximal end of the delivery catheter. It includes a plurality of electrodes that are retractable in and out of the catheter's distal end. The electrodes are in a non-deployed state when they are positioned within the delivery catheter. As they are advanced out the distal end of the catheter they become deployed, and define an ablation volume. Each electrode has a first section with a first radius of curvature, and a second section, extending beyond the first section, having a second radius of curvature or a substantially linear geometry.

[0025] Alternatively, each deployed electrode can have at least two radii of curvature that are formed when the needle is advanced through the delivery catheter's distal end and becomes positioned at a selected tissue

site.

[0026] In another embodiment, each deployed electrode has at least one radius of curvature in two or more planes. Further, the electrode deployment apparatus can include at least one deployed electrode having at least radii of curvature, and at least one deployed electrode with at least one radius of curvature in two or more planes.

[0027] In a further embodiment, the electrode deployment apparatus has at least one deployed electrode with at least one curved section that is located near the distal end of the delivery catheter, and a non-curved section which extends beyond the curved section of the deployed electrode. The electrode deployment apparatus also has at least one deployed electrode with at least two radii of curvature.

[0028] In another embodiment of the invention, each deployed electrode has at least one curved section located near the distal end of the delivery catheter, and a non-curved section that extends beyond the curved section of the deployed electrode.

[0029] An electrode template can be positioned at the distal end of the delivery catheter. It assists in guiding the deployment of the electrodes to a surrounding relationship at an exterior of a selected mass in a tissue. The electrodes can be hollow. An adjustable electrode insulator can be positioned in an adjacent, surrounding relationship to all or some of the electrodes. The electrode insulator is adjustable, and capable of being advanced and retracted along the electrodes in order to define an electrode conductive surface.

[0030] The electrode deployment apparatus can include a cam which advances and retracts the electrodes in and out of the delivery catheter's distal end. Optionally included in the delivery catheter are one or more guide tubes associated with one or more electrodes. The guide tubes are positioned at the delivery catheter's distal end.

[0031] Sources of infusing mediums, including but not limited to electrolytic and chemotherapeutic solutions, can be associated with the hollow electrodes. Electrodes can have sharpened, tapered ends in order to assist their introduction through tissue, and advancement to the selected tissue site.

[0032] The electrode deployment apparatus is removable from the delivery catheter. An obturator is initially positioned within the delivery catheter. It can have a sharpened distal end. The delivery catheter can be advanced percutaneously to an internal body organ, or site, with the obturator positioned in the delivery catheter. Once positioned, the obturator is removed, and the electrode deployment apparatus is inserted into the delivery catheter. The electrodes are in non-deployed states, and preferably compacted or spring-loaded, while positioned within the delivery catheter. They are made of a material with sufficient strength so that as the electrodes emerge from the delivery catheter's distal end they are deployed three dimensionally, in a lateral direction away from the periphery of the delivery catheter's distal end. The electrodes continue their lateral movement until the force applied by the tissue causes the needles to change their direction of travel.

[0033] Each electrode now has either, (i) a first section with a first radius of curvature, and a second section, extending beyond the first section, having a second radius of curvature or a substantially linear section, (ii) two radii of curvature, (iii) one radius of curvature in two or more planes, or (iv) a combination of two radii of curvature with one of them in two or more planes. Additionally, the electrode deployment apparatus can include one or more of these deployed geometries for the different electrodes in the plurality. It is not necessary that every electrode have the same deployed geometry.

[0034] After the electrodes are positioned around amass, such as a tumor, a variety of solutions, including but not limited to electrolytic fluids, can be introduced through the electrodes to the mass in a pre-ablation step. RF energy is applied, and the mass is desiccated. In a post-ablation procedure, a chemotherapeutic agent can then be introduced to the site, and the electrodes are then retracted back into the introducing catheter. The entire ablative apparatus can be removed, or additional ablative treatments be conducted.

[0035] Particular embodiments of the invention are described hereinafter, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of an embodiment of a tissue ablation apparatus according to the invention, including a delivery catheter, handle, and deployed electrodes.

Figure 2 is a cross-sectional view of the tissue ablation apparatus of Figure 1.

Figure 3 is a perspective view of an example of an electrode of an embodiment of the invention with two radii of curvature.

Figure 4 is a perspective view of an electrode with one radius of curvature in three planes.

Figure 5 is a perspective view of an electrode with one curved section, positioned close to the distal end of the delivery catheter, and a linear section.

Figure 6 is a perspective view of an electrode with one curved section, positioned close to the distal end of the delivery catheter, a generally first linear section, and then a second linear section that continues laterally with regard to the first linear section.

Figure 7 is a cross-section view of an example of a delivery catheter of an embodiment of the invention, with guide tubes positioned at the distal end of the delivery catheter.

Figure 8 is a cross-sectional view of an example of an electrode.

Figure 9 is a perspective view of the tissue ablation apparatus of Figure 1, with the delivery catheter being introduced percutaneously through the body and positioned at the exterior, or slightly piercing, a

liver with a tumor to be ablated.

Figure 10 is a perspective view of the tissue ablation apparatus of Figure 1 with an obturator positioned in the delivery catheter.

Figure 11 is a perspective view of the tissue ablation apparatus of Figure 10, positioned in the body adjacent to the liver, with the obturator removed.

Figure 12 is a perspective view of the tissue ablation apparatus of Figure 10, positioned in the body adjacent to the liver, and the electrode deployment apparatus, with an electrode template, is positioned in the delivery catheter in place of the obturator.

Figure 13 is a perspective view of an embodiment of an ablation apparatus of the invention, with deployed electrodes surrounding a tumor and defining an ablation volume.

Figure 14 is a perspective view of the tissue ablation apparatus of Figure 10, positioned in the body adjacent to the liver, with deployed electrodes surrounding a tumor and infusing a solution to the tumor site during a pre-ablation procedure.

Figure 15 is a perspective view of the tissue ablation apparatus of Figure 10, illustrating application of RF energy to the tumor.

Figure 16 is a perspective view of an embodiment of a tissue ablation apparatus of the invention, illustrating the electro-desiccation of the tumor.

Figure 17 is a perspective view of an embodiment of a tissue ablation apparatus of the invention, illustrating the instillation of solutions to the tumor site during a post-ablation procedure.

Figure 18 illustrates bipolar ablation between electrodes of an embodiment of the invention.

Figure 19 illustrates monopolar ablation between electrodes of an embodiment of the invention.

Figure 20 is a perspective view of an example of an ablation system of the invention, including RF and ultrasound modules, and a monitor.

Figure 21 is a block diagram of an example of an ablation system of the invention.

[0036] An embodiment of a tissue ablation apparatus 10 according to the invention is illustrated in Figure 1. Ablation apparatus 10 includes a delivery catheter 12, well known to those skilled in the art, with a proximal end 14 and a distal end 16. Delivery catheter 12 can be of the size of about 5 to 16 F. A handle 18 is removably attached to proximal end 14. An electrode deployment device is at least partially positioned within delivery catheter 12, and includes a plurality of electrodes 20 that are retractable in and out of distal end 16. Electrodes 20 can be of different sizes, shapes and configurations.

In one embodiment, they are needle electrodes, with sizes in the range of 27 to 14 gauge. Electrodes 20 are in non-deployed positions while retained in delivery catheter. In the non-deployed positions, electrodes 20 may be in a compacted state, spring loaded, generally confined or substantially straight if made of a suitable memory metal such as nitinol. As electrodes 20 are advanced out of distal end 16 they become distended in a deployed state, which defines an ablative volume, from which tissue is ablated as illustrated more fully in Figure 2. Electrodes 20 operate either in the bipolar or monopolar modes. When the electrodes are used in the bipolar mode, the ablative volume is substantially defined by the peripheries of the plurality of electrodes 20. In one embodiment, the cross-sectional width of the ablative volume is about 4 cm. However, it will be appreciated that different ablative volumes can be achieved with tissue ablation apparatus 10.

[0037] The ablative volume is first determined to define a mass, such as a tumor, to be ablated. Electrodes 20 are placed in a surrounding relationship to a mass or tumor in a predetermined pattern for volumetric ablation. An imaging system is used to first define the volume of the tumor or selected mass. Suitable imaging systems include but are not limited to, ultrasound, computerized tomography (CT) scanning, X-ray film, X-ray fluoroscopy, magnetic resonance imaging, electromagnetic imaging, and the like. The use of such devices to define a volume of a tissue mass or a tumor is well known to those skilled in the art.

[0038] With regard to the use of ultrasound, an ultrasound transducer transmits ultrasound energy into a region of interest in a patient's body. The ultrasound energy is reflected by different organs and different tissue types. Reflected energy is sensed by the transducer, and the resulting electrical signal is processed to provide an image of the region of interest In this way, the ablation volume is then ascertained, and the appropriate electrode deployment device is inserted into delivery catheter 12.

[0039] The ablative volume is substantially defined before ablation apparatus 10 is introduced to an ablative treatment position. This assists in the appropriate positioning of ablation apparatus 10. In this manner, the volume of ablated tissue is reduced and substantially limited to a defined mass or tumor, including a certain area surrounding such a tumor, that is well controlled and defined. A small area around the tumor is ablated in order to ensure that all of the tumor is ablated.

[0040] With reference again to Figure 2, electrode sections 20(a) are in deployed states when they are introduced out of distal end 16. Although electrodes 20 are generally in a non-distended configuration in the non-deployed state while positioned in delivery catheter 12, they can also be distended. Generally, electrode sections 20(b) are in retained positions while they are non-deployed. This is achieved by a variety of methods including but not limited to, (i) the electrodes are presprung, confined in delivery catheter 12, and only become sprung (expanded) as they are released from delivery catheter 12, (ii) the electrodes are made of a memory metal, as explained in further detail below, (iii) the electrodes are made of a selectable electrode material which gives them an expanded shape outside of deliv-

ery catheter 12, or (iv) delivery catheter 12 includes guide tubes which serve to confine electrodes 12 within delivery catheter 12 and guide their direction of travel outside of the catheter to form the desired, expanded ablation volume. As shown in Figure 2, electrodes 20 are pre-sprung while retained in delivery catheter 12. This is the non-deployed position. As they are advanced out of delivery catheter 12 and into tissue, electrodes 20 become deployed and begin to "fan" out from distal end 16, moving in a lateral direction relative to a longitudinal axis of delivery catheter 12. As deployed electrodes 20 continue their advancement, the area of the fan increases and extends beyond the diameter of distal end 16.

[0041] Significantly, each electrode 20 is distended in a deployed position, and collectively, the deployed electrodes 20 define a volume of tissue that will be ablated. As previously mentioned, when it is desired to ablate a tumor, either benign or malignant, it is preferable to ablate an area that is slightly in excess to that defined by the exterior surface of the tumor. This improves the chances that all of the tumor is eradicated.

[0042] Deployed electrodes 20 can have a variety of different deployed geometries including but not limited to, (i) a first section with a first radius of curvature, and a second section, extending beyond the first section, having a second radius of curvature or a substantially linear geometry, (ii) at least two radii of curvature, (iii) at least one radius of curvature in two or more planes, (iv) a curved section, with an elbow, that is located near distal end 16 of delivery catheter, and a non-curved section that extends beyond the curved section, or (v) a curved section near distal end 16, a first linear section, and then another curved section or a second linear section that is angled with regard to the first linear section. Deployed electrodes 20 need not be parallel with respect to each other. The plurality of deployed electrodes 20, which define a portion of the needle electrode deployment device, can all have the same deployed geometries, i.e., all with at least two radii of curvature, or a variety of geometries, i.e., one with two radii of curvature, a second one with one radius of curvature in two planes, and the rest a curved section near distal end 16 of delivery catheter 12 and a non-curved section beyond the curved section.

[0043] A cam 22, or other actuating device, can be positioned within delivery catheter and used to advance and retract electrodes 20 in and out of delivery catheter 12. The actual movement of cam can be controlled at handle 18. Suitable cams are of conventional design, well known to those skilled in the art.

[0044] The different geometric configurations of electrodes 20 are illustrated in Figures 3 through 6. In Figure 3, electrode 20 has a first radius of curvature 20(c) and a second radius of curvature 20(d). It can include more than two radii of curvature. As shown in Figure 4, electrode 20 has at least one radius of curvature which extends to three planes. In Figure 5, each electrode has a first curved section 20(e) which is near distal end 16 of delivery catheter 12. A first generally linear section 20(f) extends beyond curved section 20(e), and the two meet at an elbow 20(g). The electrodes 20 can serve as anodes and cathodes. The plurality of electrodes 20 can have linear sections 20(f) that are generally parallel to each other, or they can be non-parallel. Figure 6 illustrates an electrode 20 that includes a first curved section 20(e) positioned near distal end 16 of delivery catheter 12, a first linear section 20(f), and a second linear section 20(h) which extends beyond first linear section 20(f). Section 20(h) can be linear, curved, or a combination of the two. The plurality of electrodes 20 illustrated in Figure 6 can have parallel or non-parallel first linear sections 20(f).

[0045] In one embodiment of the invention, electrodes 20 are spring-loaded, and compacted in their non-deployed positions. As electrodes 20 are advanced out of distal end 16 of delivery catheter 12, they become deployed and fan out. Electrodes 20 continue this fanning out direction until the resistance of the tissue overcomes the strength of the material forming electrode 20. This causes electrode 20 to bend and move in a direction inward relative to its initial outward fanning direction. The bending creates curved sections 20(c) and 20(d) of Figure 3, and can also result in the formation of the other electrode 20 geometries of Figures 4, 5 and 6. The extent of electrode 20 fan like travel is dependent on the strength of the material from which it is made. Suitable electrode materials include stainless steel, platinum, gold, silver, copper and other electromagnetic conducting materials including conductive polymers. Preferably, electrode 20 is made of stainless steel or nickel titanium and has dimensions of about 27 to 14 gauge.

[0046] In one embodiment, electrode 20 is made of a memory metal, such as nickel titanium, commercially available from Raychem Corporation, Menlo Park, California. Additionally, a resistive heating element can be positioned in an interior lumen of electrode 20. Resistive heating element can be made of a suitable metal that transfers heat to electrode 20, causing deployed electrode 20 to become deflected when the temperature of electrode 20 reaches a level that causes the electrode material, such as a memory metal, to deflect, as is well known in the art. Not all of electrode 20 need be made of a memory metal. It is possible that only that distal end portion of electrode 20, which is introduced into tissue, be made of the memory metal in order to effect the desired deployed geometrical configuration. Additionally, mechanical devices, including but not limited to steering wires, can be attached to the distal end of electrode 20 to cause it to become directed, deflected and move about in a desired direction about the tissue, until it reaches its final resting position to ablate a tissue mass.

[0047] Optionally included in the delivery catheter are one or more guide tubes 24, Figure 7, which serve to direct the expansion of electrodes 20 in the fan pattern as they are advanced out of distal end 16 of the delivery catheter 12. Guide tubes 24 can be made of stainless

steel, spring steel and thermal plastics including but not limited to nylon and polyesters, and are of sufficient size and length to accommodate the electrodes to a specific site in the body.

[0048] Figure 8 illustrates one embodiment of electrode 20 with a sharpened distal end 24. By including a tapered, or piercing end 24, the advancement of electrode 20 through tissue is easier. Electrode 20 can be segmented, and include a plurality of fluid distribution ports 26, which can be evenly formed around all or only a portion of electrode 20. Fluid distribution ports 26 are formed in electrode 20 when it is hollow and permit the introduction and flow of a variety of fluidic mediums through electrode 20 to a desired tissue site. Such fluidic mediums include, but are not limited to, electrolytic solutions, pastes or gels, as well as chemotherapeutic agents. Examples of suitable conductive gels are carboxymethylcellulose gels made from aqueous electrolyte solutions such as physiological saline solutions, and the like.

[0049] The size of fluid distribution ports 26 can vary, depending on the size and shape of electrode 20. Also associated with electrode 20 is an adjustable insulator sleeve 28 that is slidable along an exterior surface of electrode 20. Insulator sleeve 28 is advanced and retracted along electrode 20 in order to define the size of a conductive surface of electrode 20. Insulator sleeve 28 is actuated at handle 18 by the physician, and its position along electrode 20 is controlled. When electrode 20 moves out of delivery catheter 12 and into tissue, insulator sleeve 28 can be positioned around electrode 20 as it moves its way through the tissue. Alternatively, insulator sleeve 28 can be advanced along a desired length of electrode 20 after electrode 20 has been positioned around a targeted mass to be ablated. Insulator sleeve is thus capable of advancing through tissue along with electrode 20, or it can move through tissue without electrode 20 providing the source of movement. Thus, the desired ablation volume is defined by deployed electrodes 20, as well as the positioning of insulator sleeve 28 on each electrode. In this manner, a very precise ablation volume is created. Suitable materials that form insulator sleeve include but are not limited to nylon, polyimides, other thermoplastics, and the like.

[0050] Figure 9 illustrates a percutaneous application of tissue ablation apparatus 10. Tissue ablation apparatus 10 can be used percutaneously to introduce electrodes 20 to the selected tissue mass or tumor. Electrodes 20 can remain in their non-deployed positions while being introduced percutaneously into the body, and delivered to a selected organ which contains the selected mass to be ablated. Delivery catheter 12 is removable from handle 18. When it is removed, electrode deployment device (the plurality of electrodes 20) can be inserted and removed from delivery catheter 12. An obturator 30 is inserted into delivery catheter 12 initially if a percutaneous procedure is to be performed. As shown in Figure 10, obturator 30 can have a sharpened distal end 32 that pierces tissue and assists the introduction of delivery catheter 12 to a selected tissue site. The selected tissue site can be a body organ with a tumor or other mass, or the actual tumor itself.

[0051] Obturator 30 is then removed from delivery catheter 12 (Figure 11). Electrode deployment device is then inserted into delivery catheter 12, and the catheter is then reattached to handle 18 (Figure 12). As illustrated in Figure 12, electrode deployment device can optionally include an electrode template 34 to guide the deployment of electrodes 20 to a surrounding relationship at an exterior of a selected mass in the tissue.

[0052] Electrodes 20 are then advanced out of distal end 16 of delivery catheter 12, and become deployed to form a desired ablative volume which surrounds the mass. In Figure 13, delivery catheter 12 is positioned adjacent to the liver. Electrode deployment device is introduced into delivery catheter 12 with electrode template 34. Electrode deployment device now pierces the liver, and cam 22 advances electrodes 20 out of delivery catheter 12 into deployed positions. Each individual electrode 20 pierces the liver and travels through it until it is positioned in a surrounding relationship to the tumor. The ablative volume is selectable, and determined first by imaging the area to be ablated. The ablative volume is defined by the peripheries of all of the deployed electrodes 20 that surround the exterior of the tumor. Once the volume of ablation is determined, then an electrode set is selected which will become deployed to define the ablation volume. A variety of different factors are important in creating an ablation volume. Primarily, different electrodes 20 will have various degrees of deployment, based on type of electrode material, the level of prespringing of the electrodes and the geometric configuration of the electrodes in their deployed states. Tissue ablation apparatus 10 permits different electrode 20 sets to be inserted into delivery catheter 12, in order to define a variety of ablation volumes.

[0053] Prior to ablation of the tumor, a pre-ablation step can be performed. A variety of different solutions, including electrolytic solutions such as saline, can be introduced to the tumor site, as shown in Figure 14. Figure 15 illustrates the application of RF energy to the tumor. Electrode insulator 28 is positioned on portions of electrodes 20 where there will be no ablation. This further defines the ablation volume. The actual electrodesiccation of the tumor, or other targeted masses or tissues, is shown in Figure 16. Again, deployed electrodes 20, with their electrode insulators 28 positioned along sections of the electrodes, define the ablation volume, and the resulting amount of mass that is desiccated.

[0054] Optionally following desiccation, electrodes 20 can introduce a variety of solutions in a post-ablation process. This step is illustrated in Figure 17. Suitable solutions include but are not limited to chemotherapeutic agents.

[0055] Figure 18 illustrates tissue ablation apparatus

10 operated in a bipolar mode. Its monopolar operation is shown in Figure 19. Each of the plurality of electrodes 20 can play different roles in the ablation process. There can be polarity shifting between the different electrodes.

[0056] A tissue ablation system 36, which can be modular, is shown in Figure 20 and can include a display 38. Tissue ablation system 36 includes the RF energy source, and can also include microwave source, ultrasound source, visualization devices such as cameras and VCR's, electrolytic and chemotherapeutic solution sources, and a controller which can be used to monitor temperature or impedance. One of the deployed electrodes 20 can be a microwave antenna coupled to a microwave source. This electrode can initially be coupled to RF power source 42 and is then switched to the microwave source

[0057] Referring now to Figure 21, a power supply 40 delivers energy into RF power generator (source) 42 and then to electrodes 20 of tissue ablation apparatus 10. A multiplexer 46 measures current, voltage and temperature (at numerous temperature sensors which can be positioned on electrodes 20). Multiplexer 46 is driven by a controller 48, which can be a digital or analog controller, or a computer with software. When controller 48 is a computer, it can include a CPU coupled through a system bus. This system can include a keyboard, disk drive, or other non-volatile memory systems, a display, and other peripherals, as known in the art. Also coupled to the bus are a program memory and a data memory.

[0058] An operator interface 50 includes operator controls 52 and display 38. Controller 48 is coupled to imaging systems, including ultrasound transducers, temperature sensors, and viewing optics and optical fibers, if included.

[0059] Current and voltage are used to calculate impedance. Diagnostics are done through ultrasound, CT scanning, or other methods known in the art Imaging can be performed before, during and after treatment.

[0060] Temperature sensors measure voltage and current that is delivered. The output of these sensors is used by controller 48 to control the delivery of RF power. Controller 48 can also control temperature and power. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 38, as well as a pre-set amount of energy to be delivered can also be profiled.

[0061] Feedback can be the measurement of impedance or temperature. and occurs either at controller 48 or at electromagnetic energy source 42, e.g., RF or microwave, if it incorporates a controller. For impedance measurement, this can be achieved by supplying a small amount of non-ablation RF energy. Voltage and current are then measured.

[0062] Circuitry, software and feedback to controller 48 result in process control and are used to change, (i) power, including RF. ultrasound, and the like, (ii) the duty cycle (on-off and wattage), (iii) monopolar or bipolar energy delivery, (iv) chemotherapeutic and electrolytic solution delivery, flow rate and pressure and (v) determine when ablation is completed through time, temperature and/or impedance. These process variables can be controlled and varied based on temperature monitored at multiple sites, and impedance to current flow that is monitored, indicating changes in current carrying capability of the tissue during the ablative process.

[0063] There has been described embodiments of RF tumor treatment apparatus that are useful for minimally invasive procedures. Embodiments have been illustrated where the exterior of the tumor is surrounded with treatment electrodes, defining a controlled ablation volume, and subsequently the electrodes deliver a controlled amount of RF energy. Embodiments have been illustrated with infusion capabilities during a pre-ablation step, and after ablation the surrounding tissue can be preconditioned with electromagnetic ("EM") energy at hyperthermia temperatures less than 45 degrees. This would provide for the synergistic affects of chemotherapy and the instillation of a variety of fluids at the tumor site after local ablation and hyperthermia.

[0064] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated.

Claims

1. An ablation apparatus, comprising:

   an introducer having a proximal end, means for holding the introducer, a lumen and a distal end sufficiently sharp to penetrate tissue;
   an energy delivery device including a first RF electrode with a tissue piercing distal portion and a second RF electrode with a tissue piercing distal portion, the first and second RF electrodes being positionable in the introducer as the introducer is advanced through tissue and deployable with curvature from the introducer at a selected tissue site in a lateral direction away from the periphery of the introducer; and
   an RF electrode advancement member coupled to the first and second RF electrodes and configured to advance the first and second RF electrodes through tissue.

2. The apparatus of Claim 1, wherein the introducer is configured to receive a fluidic medium.

3. The apparatus of Claim 2, wherein the first RF electrode includes a hollow lumen configured to receive a fluidic medium.

4. The apparatus of Claim 3, wherein the second RF electrode includes a hollow lumen configured to receive a fluidic medium.

5. The apparatus of any preceding claim, further comprising:
an insulator positioned in a surrounding relation to at least a portion of the first RF electrode.

6. The apparatus of any preceding claim, further comprising:
an insulator positioned in a surrounding relation to at least a portion of the second RF electrode.

7. The apparatus of any preceding claim, further comprising:
an obturator.

8. The apparatus of Claim 7, wherein the obturator has a piercing distal end.

9. The apparatus of Claim 7 or Claim 8, wherein the obturator is positionable in the elongated member.

10. The apparatus of any preceding claim, wherein the first RF electrode is formed of a shaped memory alloy.

11. The apparatus of any one of Claims 1 to 9, wherein the first RF electrode is formed of stainless steel.

12. The apparatus of any preceding claim, wherein the first and second RF electrodes are deployable to surround a selected tissue site.

13. The apparatus of Claim 12, wherein the first and second RF electrodes are deployable to surround a tumor.

14. The apparatus of Claim 13, wherein the introducer is introducable through the selected tissue site and the first and second RF electrodes are deployable to surround the selected tissue site.

15. The apparatus of any preceding claim, further comprising:
a sensor coupled to the first RF electrode.

16. The apparatus of Claim 15, wherein the sensor is a thermal sensor.

17. The apparatus of any preceding claim, further comprising:
a sensor coupled to the introducer.

18. The apparatus of any one of Claims 15 to 17, further comprising:
a feedback control coupled to the sensor and to the first RF electrode.

19. The apparatus of any preceding claim, further comprising:
an impedance measurement apparatus.

20. The apparatus of Claim 19, wherein the impedance measurement apparatus comprises:

a controller;
a microprocessor coupled to the controller; and
a feedback control including circuitry, wherein RF energy is delivered to a tissue site, a measurement of a voltage and current of a tissue site are determined and the current adjusted according to the measurement of the voltage and current of the tissue site.

21. The apparatus of any preceding claim, wherein the energy delivery device further includes a third RF electrode with a tissue piercing distal portion, the first second and third RF electrodes being positionable in the introducer as the introducer is advanced through tissue and deployable three dimensionally with curvature from the introducer at a selected tissue site in a lateral direction away from the periphery of the introducer, the RF electrode advancement member being coupled to the first, second and third RF electrodes and configured to advance the first and second RF electrodes through tissue.

22. The apparatus of Claim 21, wherein the first, second and third RF electrodes are deployable to surround a selected tissue site.

23. The apparatus of Claim 22, wherein the first, second and third RF electrodes are deployable to surround a tumor.

24. The apparatus of Claim 21, wherein the introducer is introduced through the selected tissue site and the first, second and third RF electrodes are deployable to surround the selected tissue site.

25. The apparatus of any preceding claim wherein each RF electrode has a tissue piercing distal end.

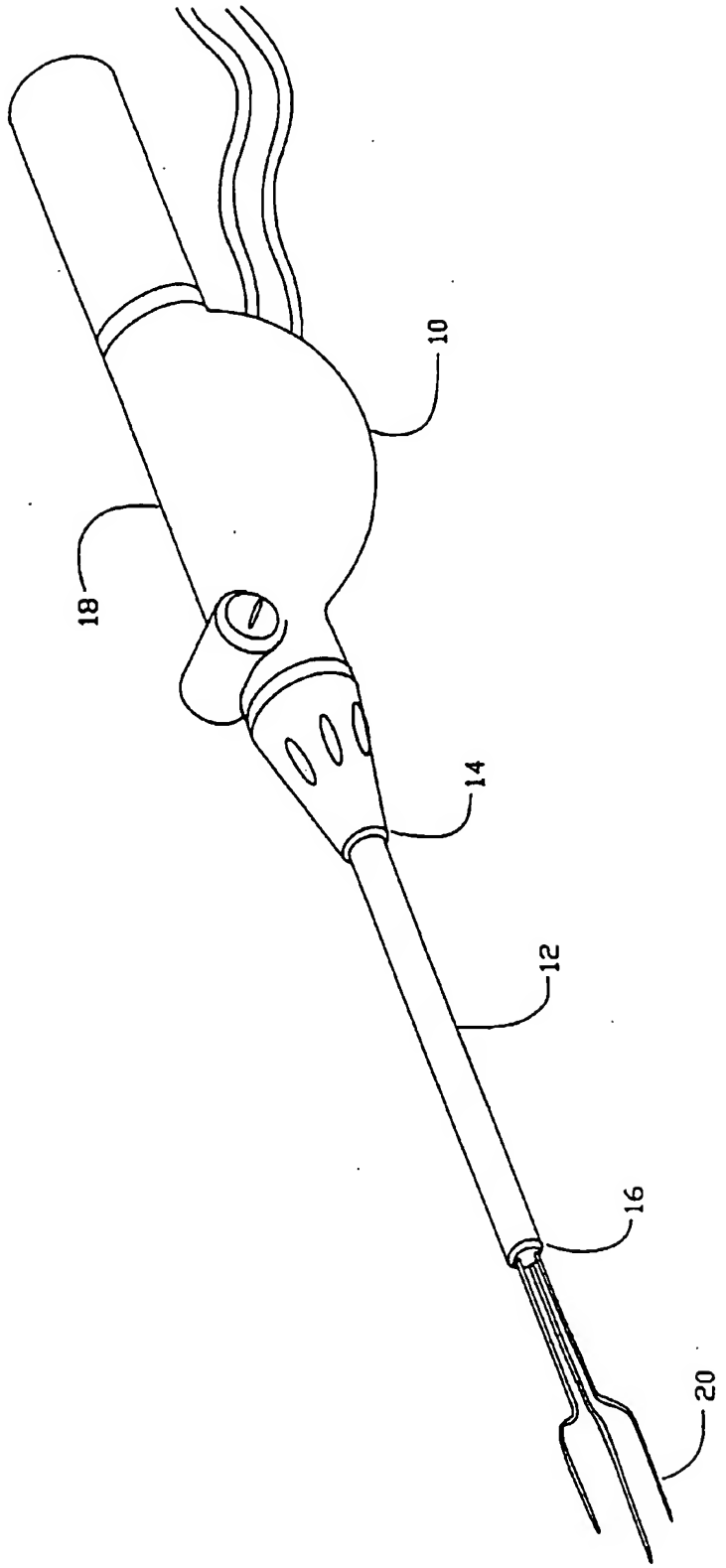


FIG. 1

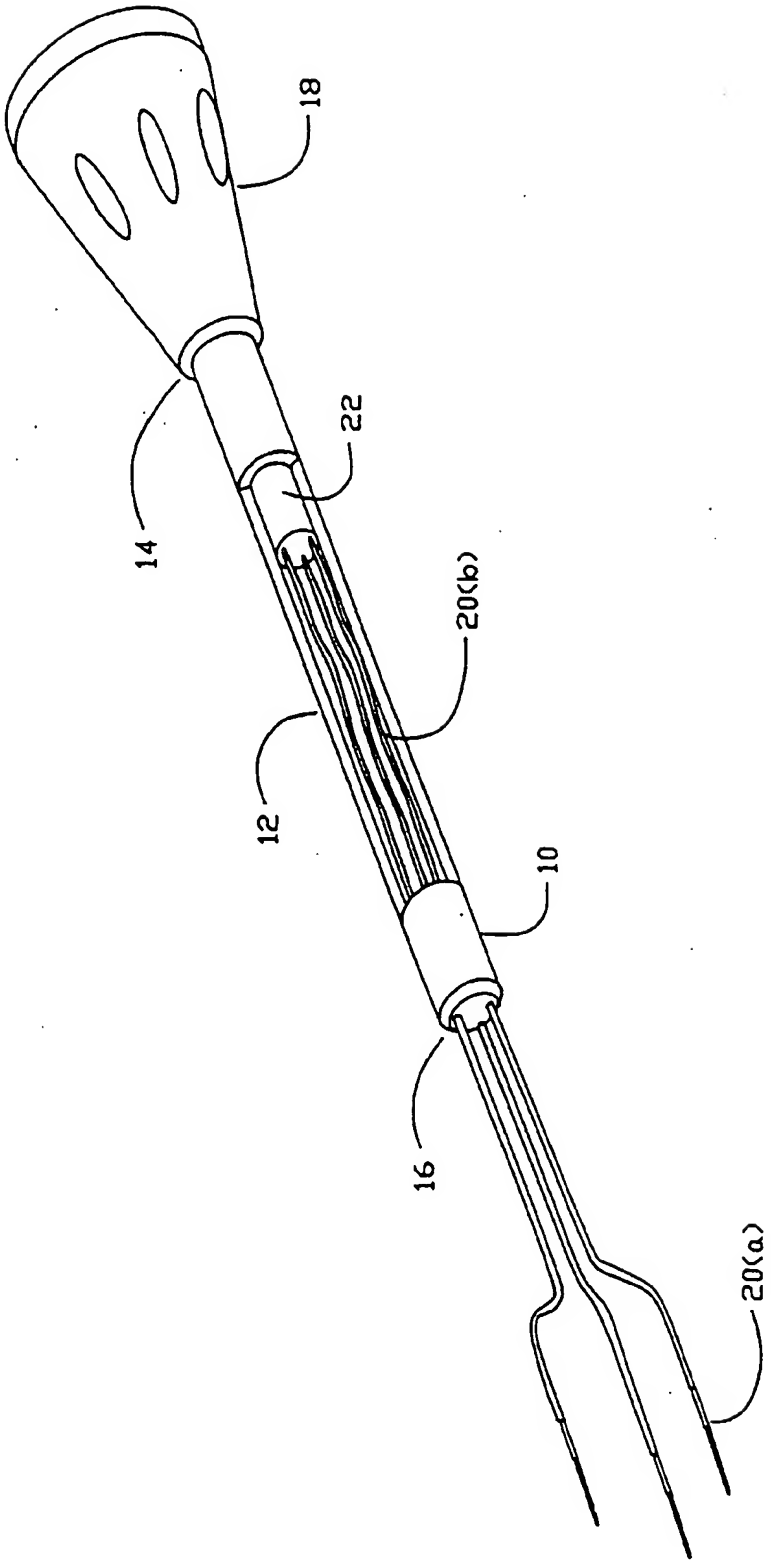


FIG.2

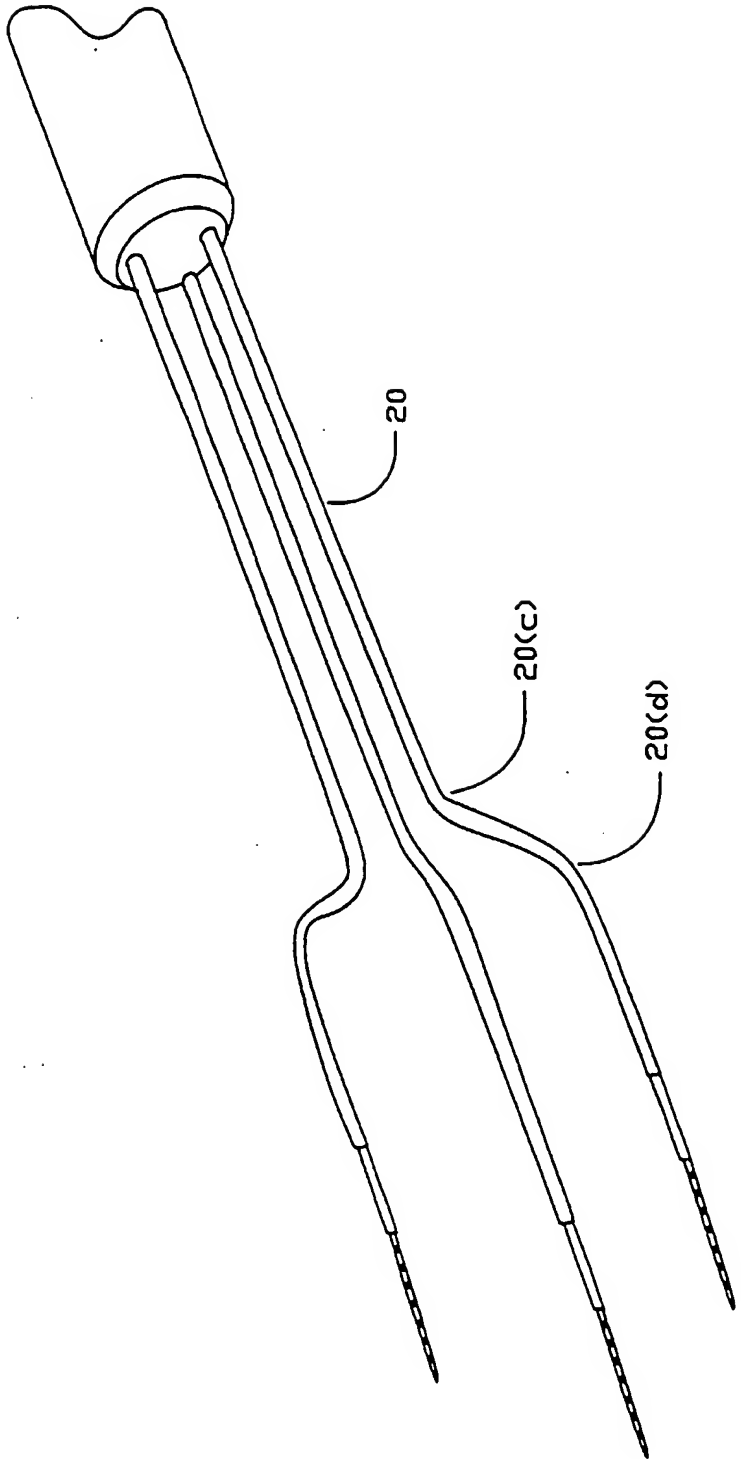
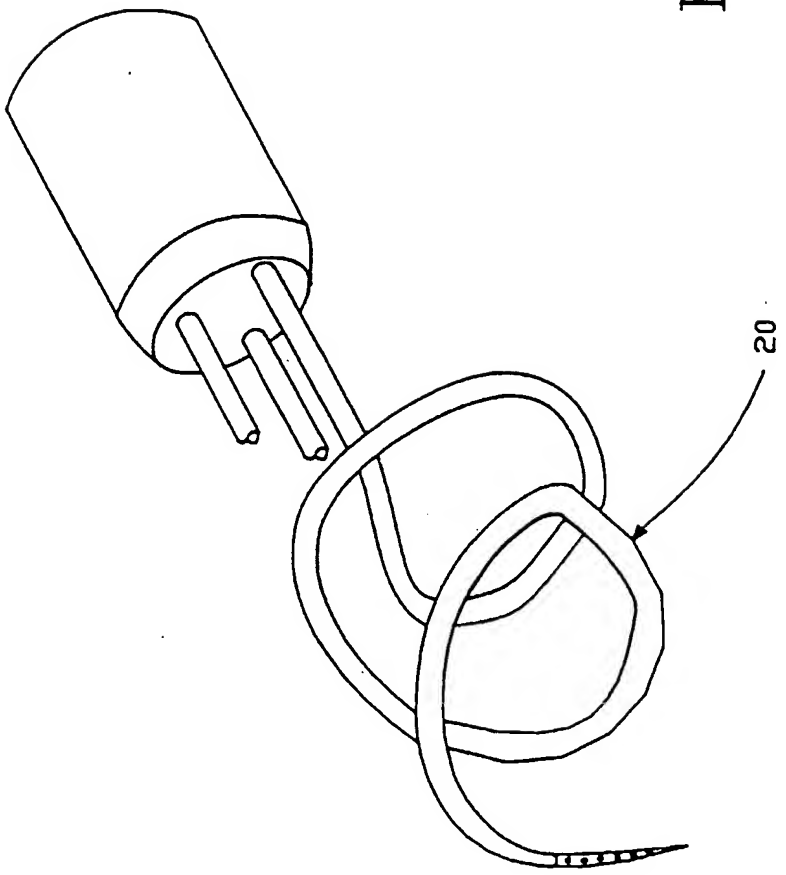


FIG.3

FIG.4



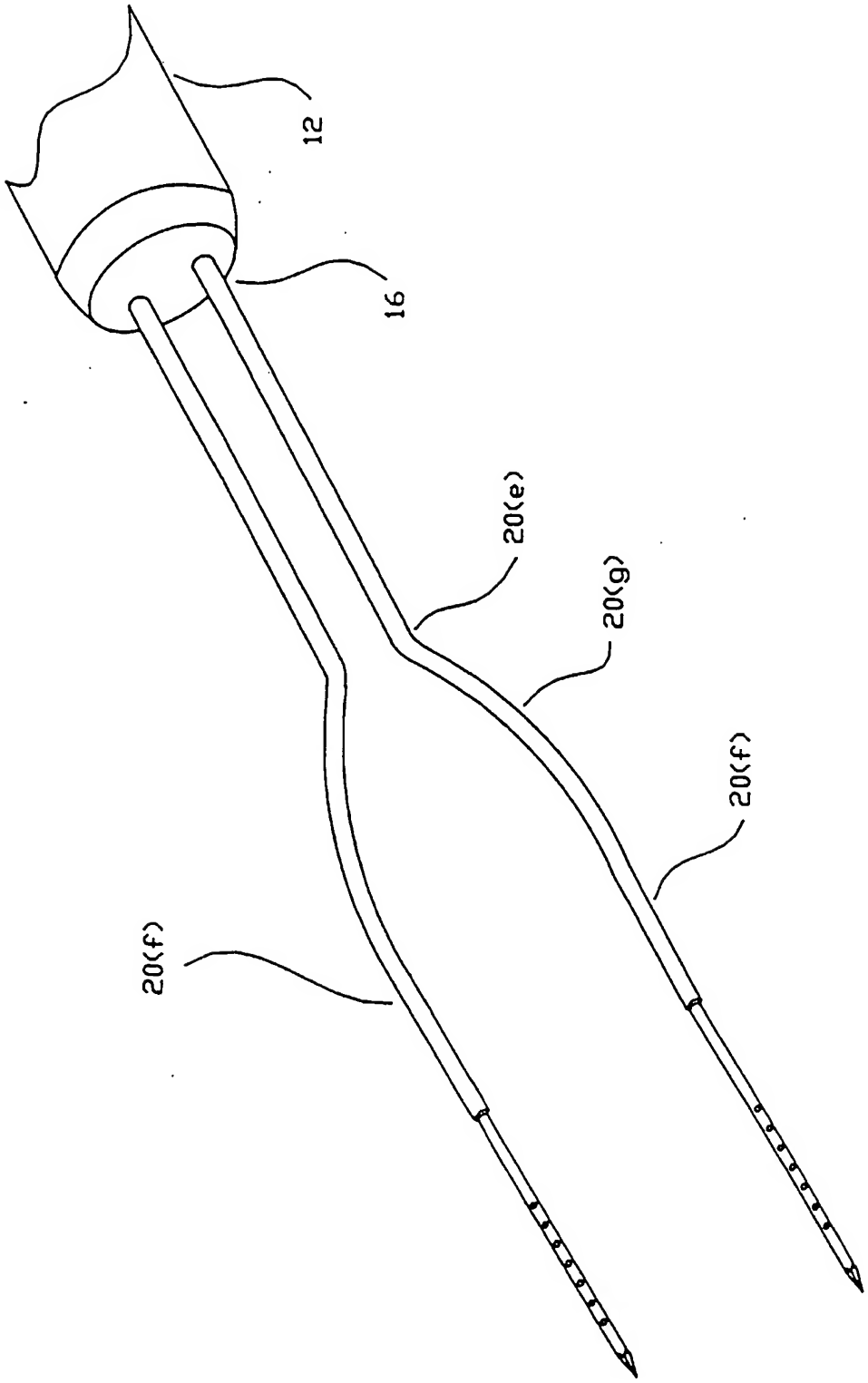


FIG.5

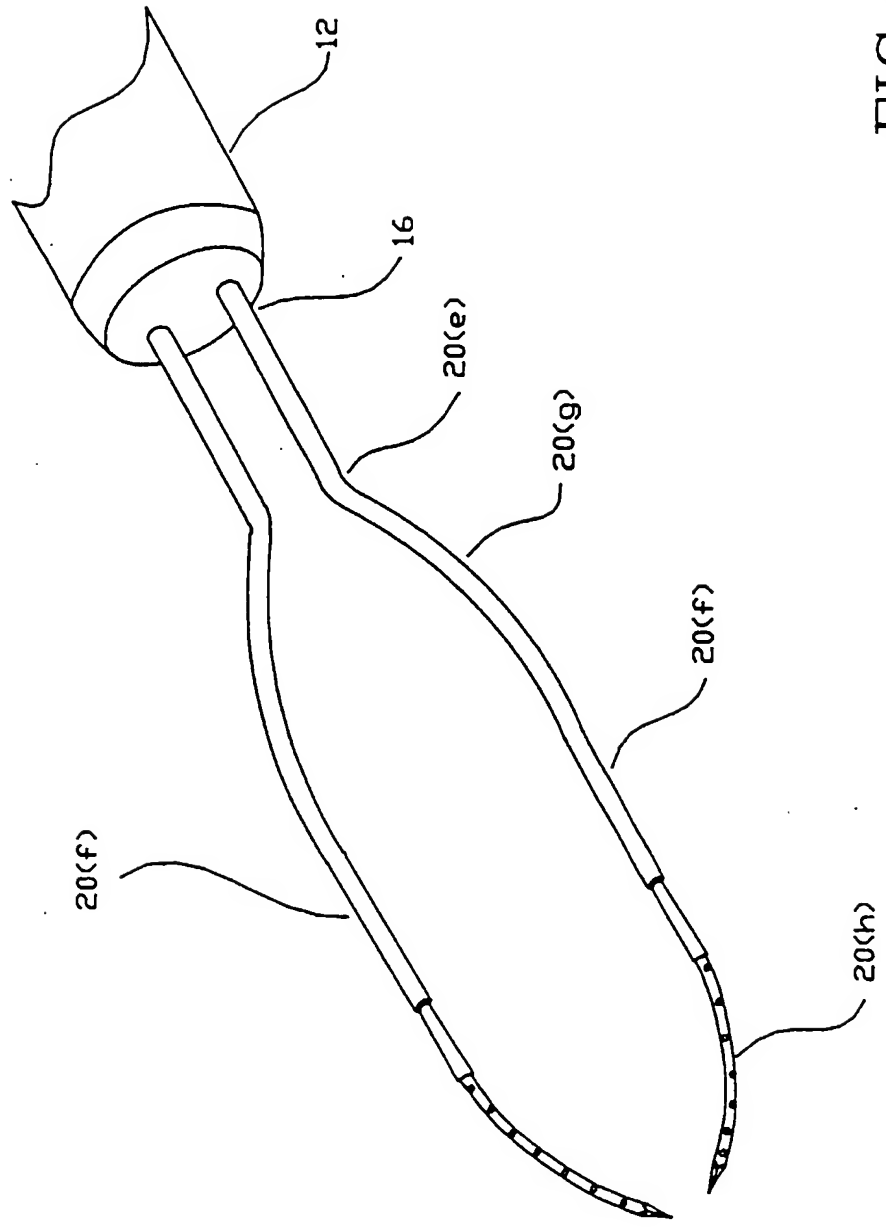


FIG.6

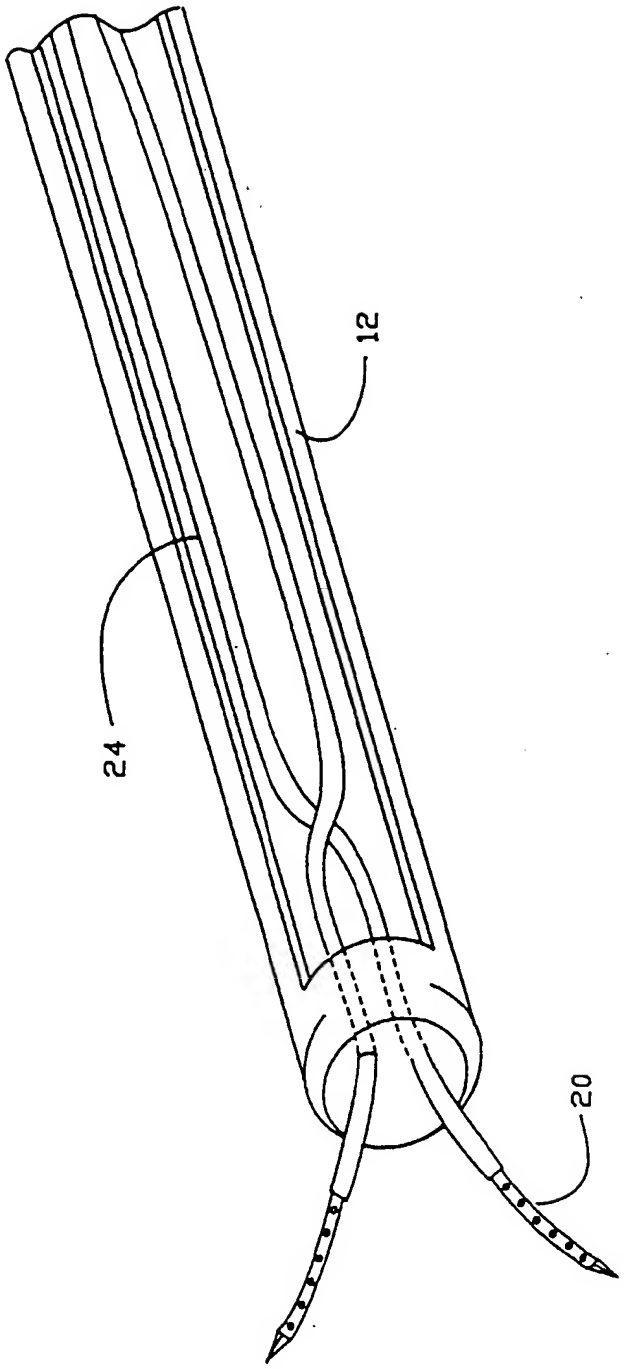


FIG.7

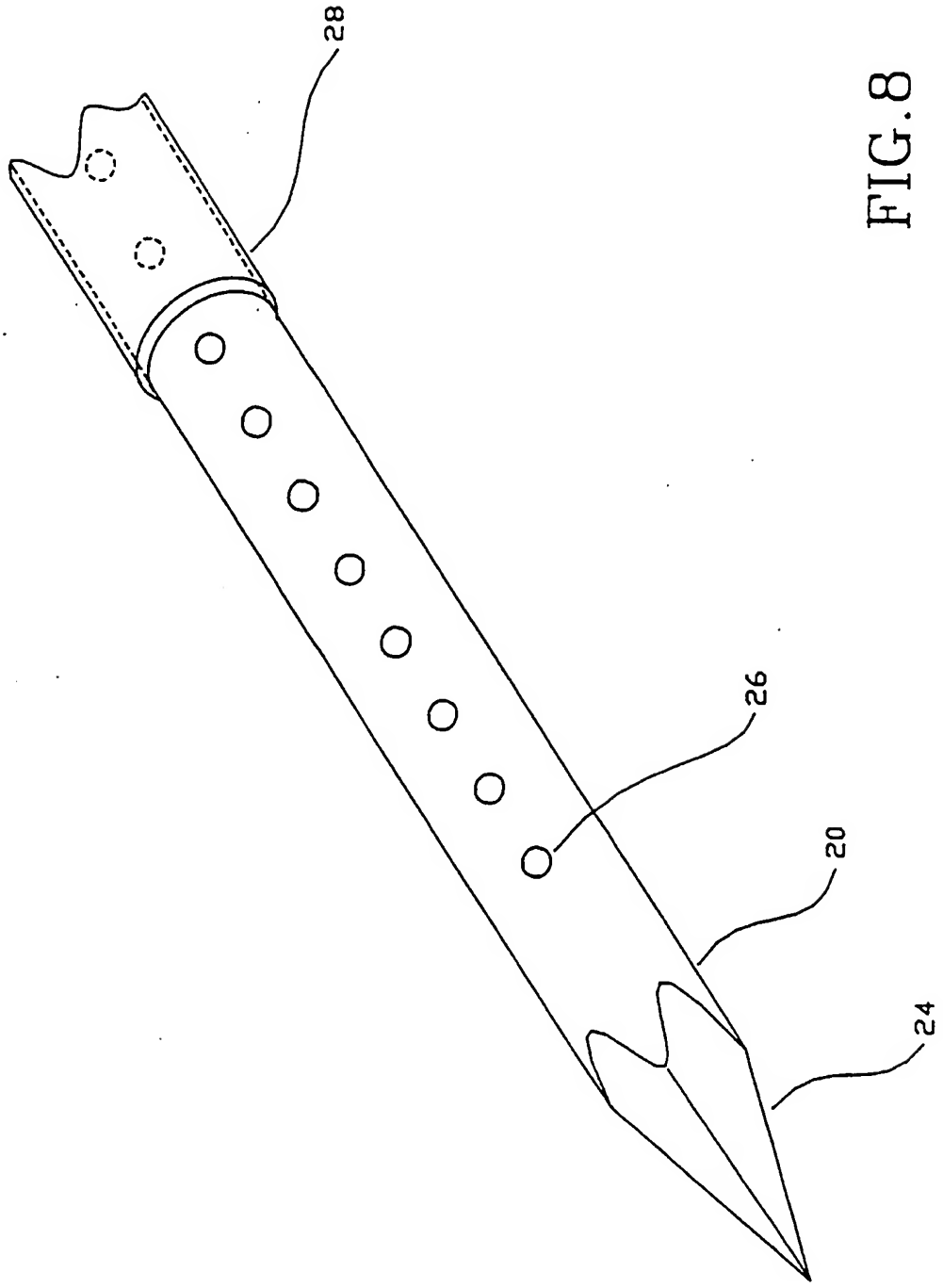


FIG.8

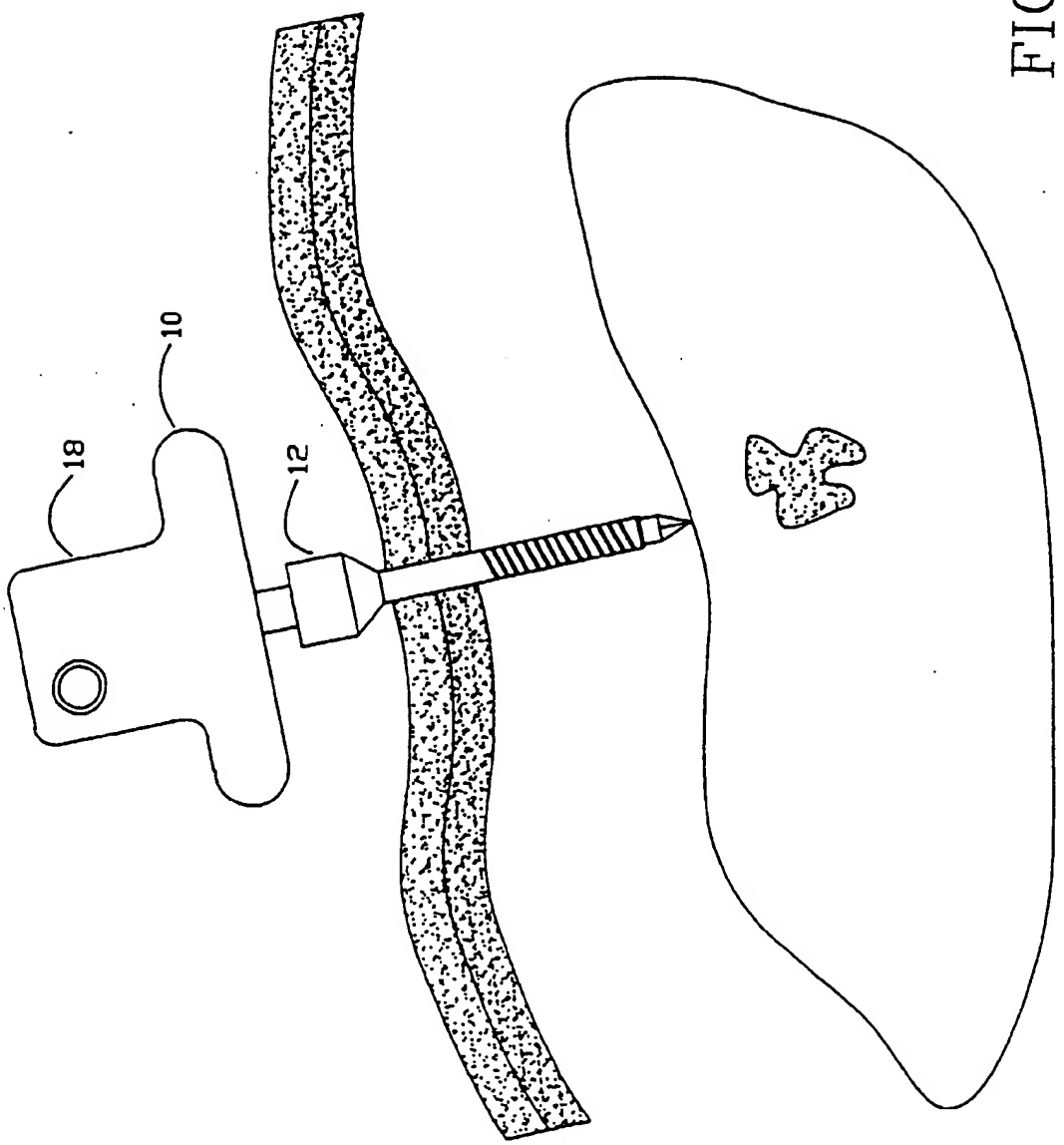


FIG.9

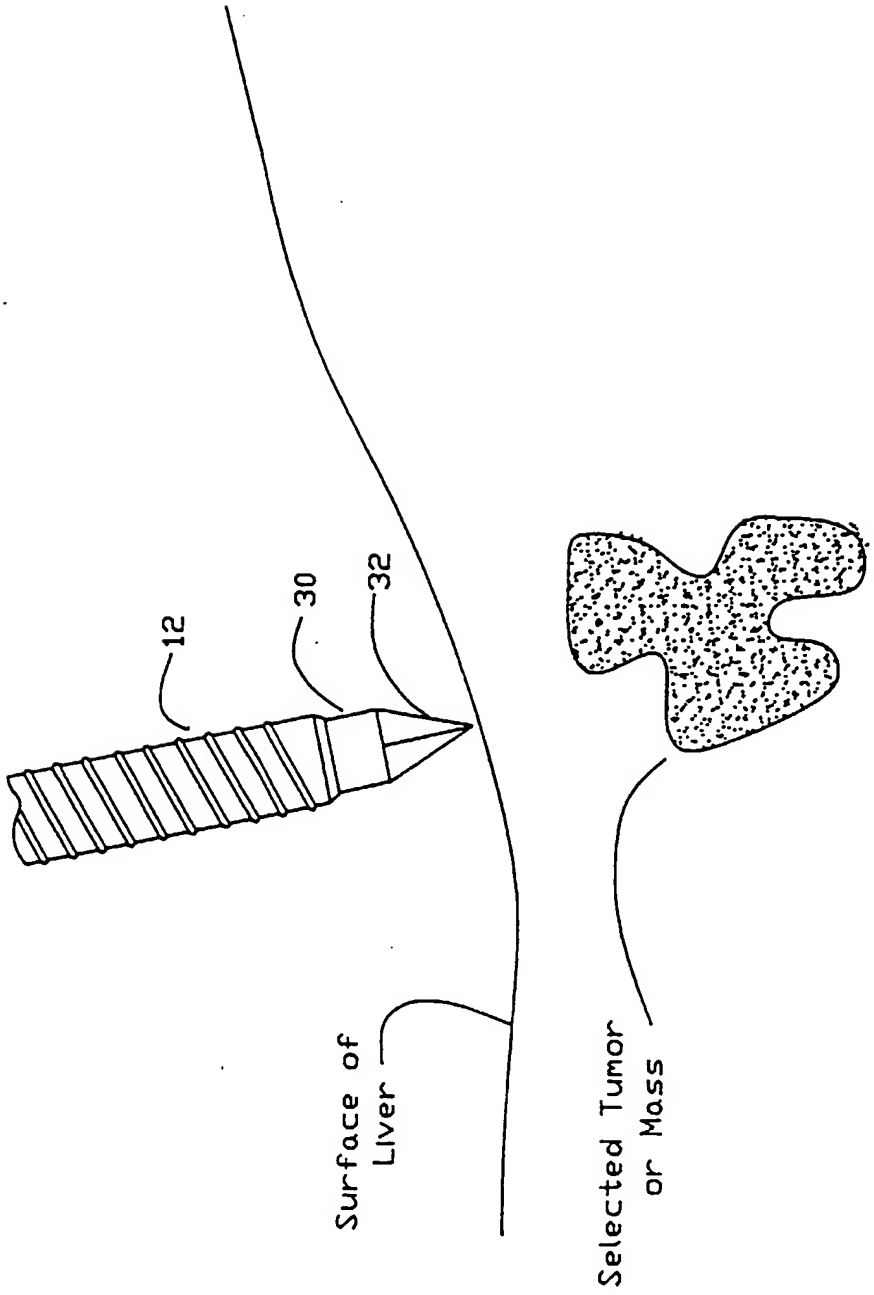


FIG. 10

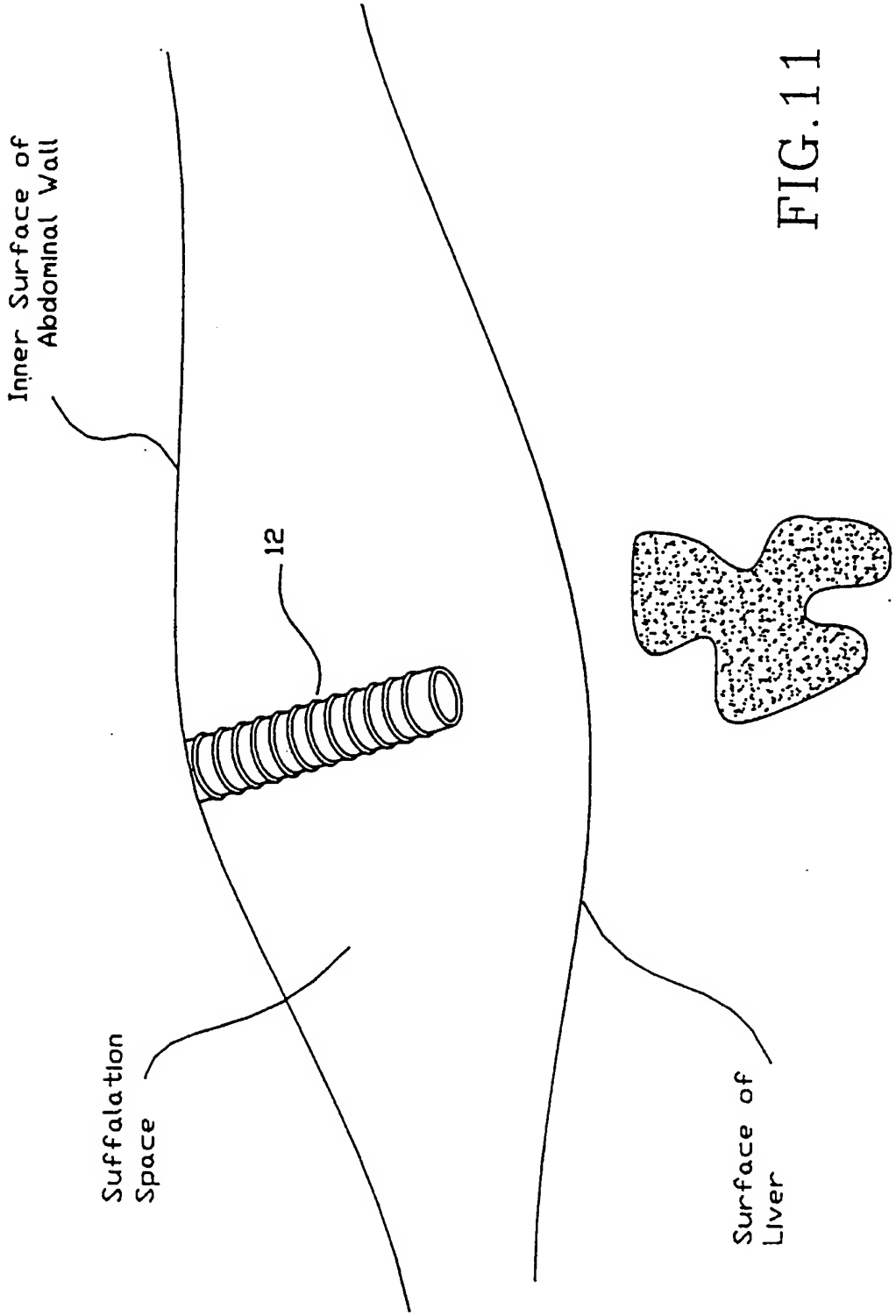
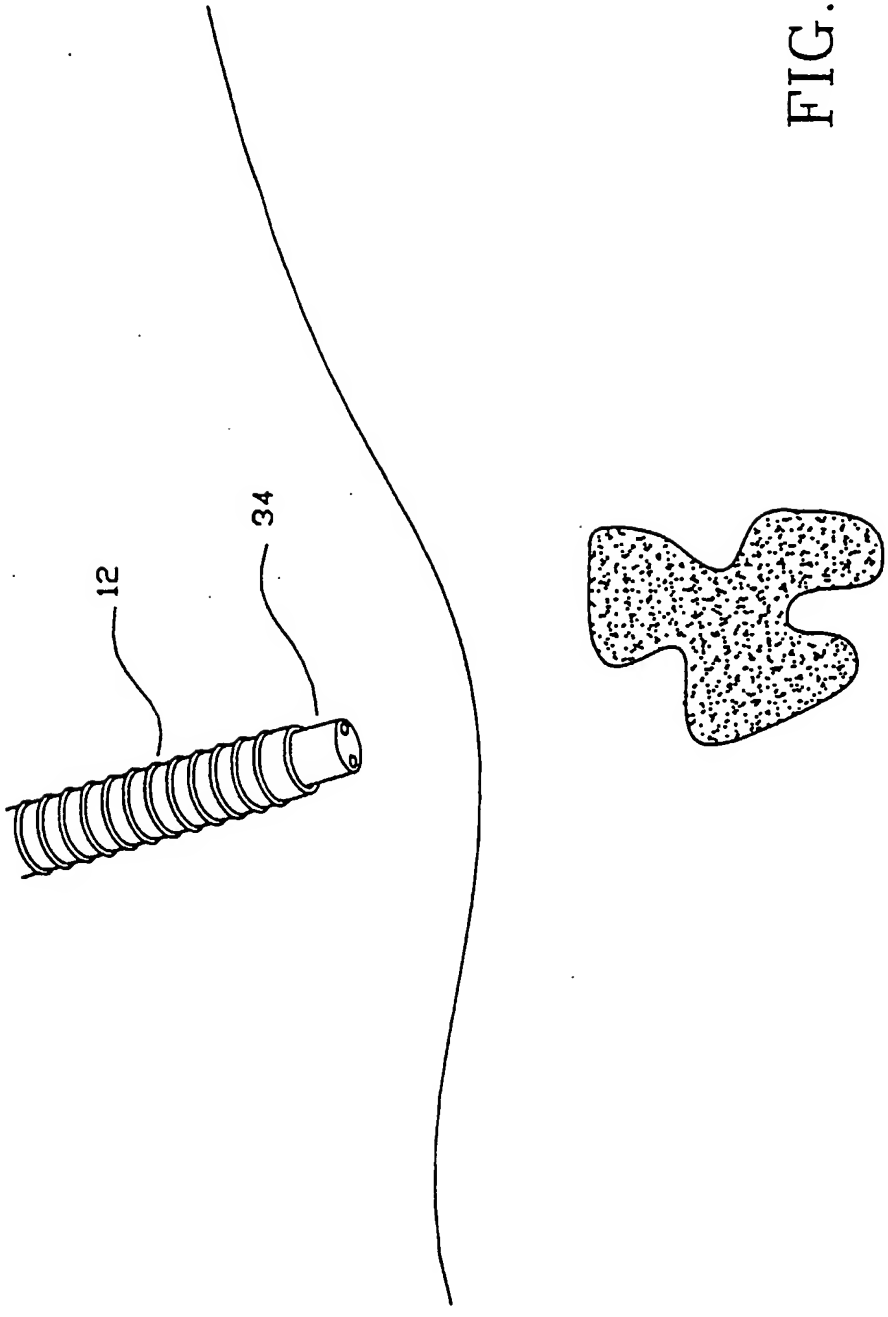

Inner Surface of Abdominal Wall
12
Suffalation Space
Surface of Liver

FIG. 11

FIG. 12



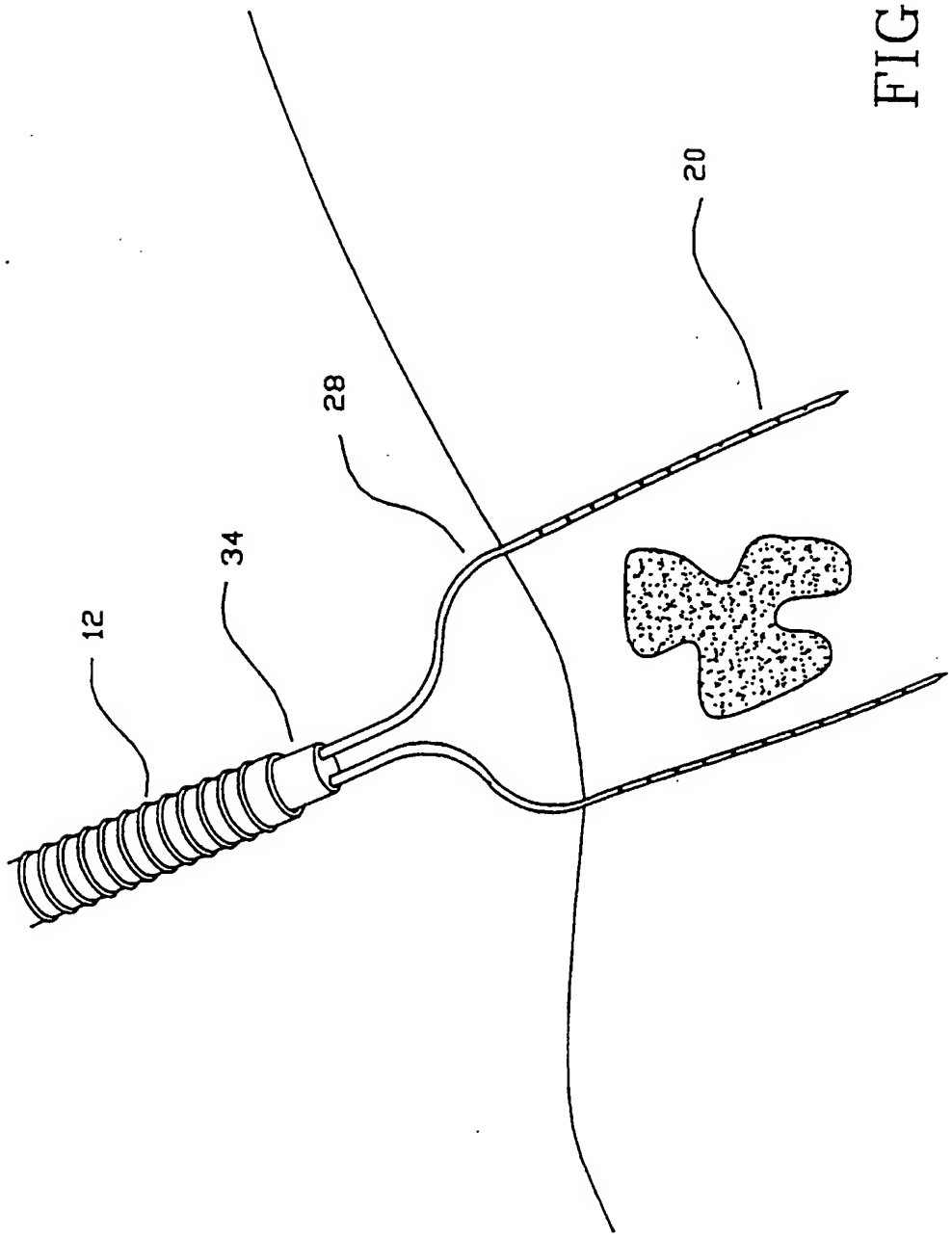


FIG. 13

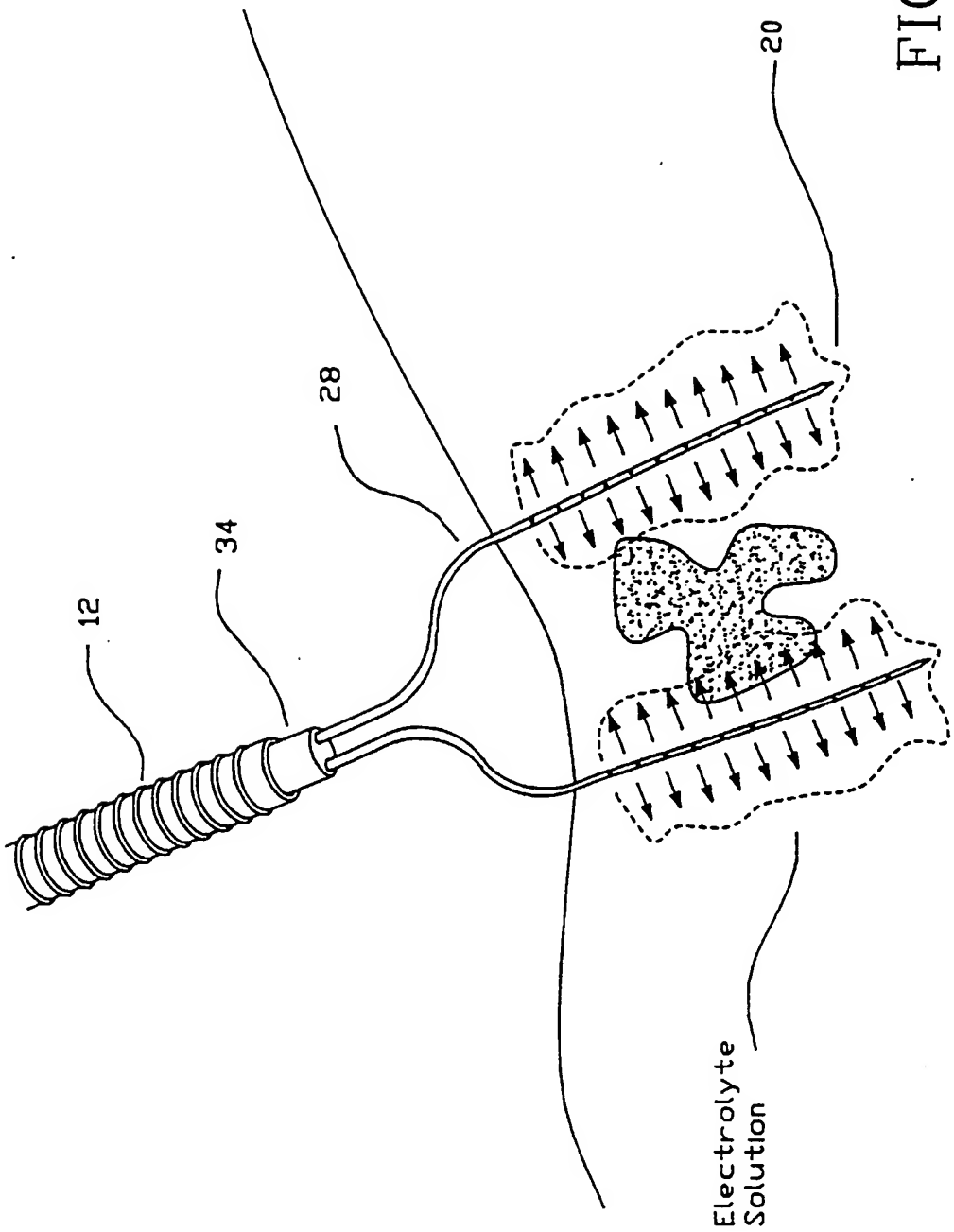


FIG. 14

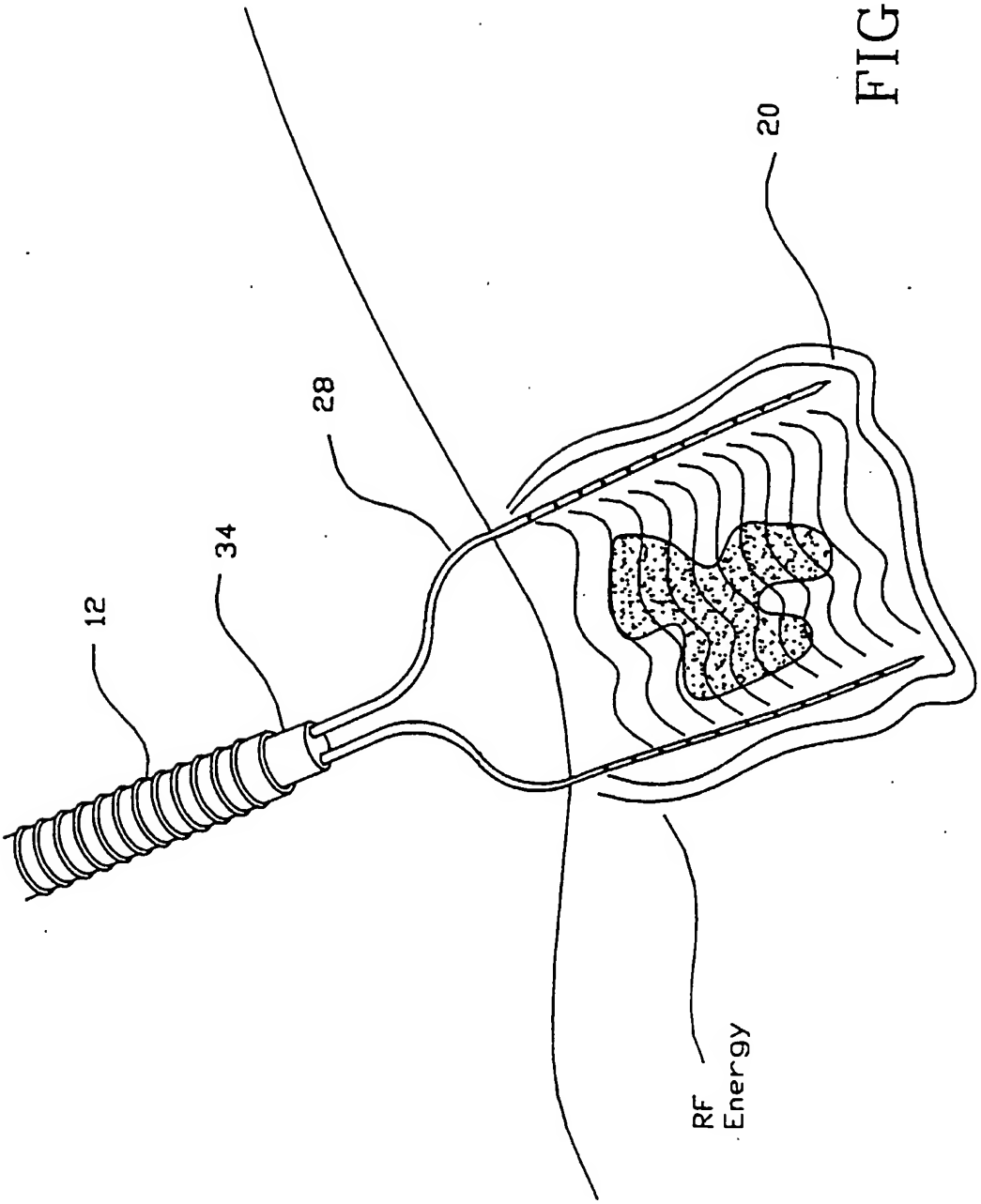


FIG.15

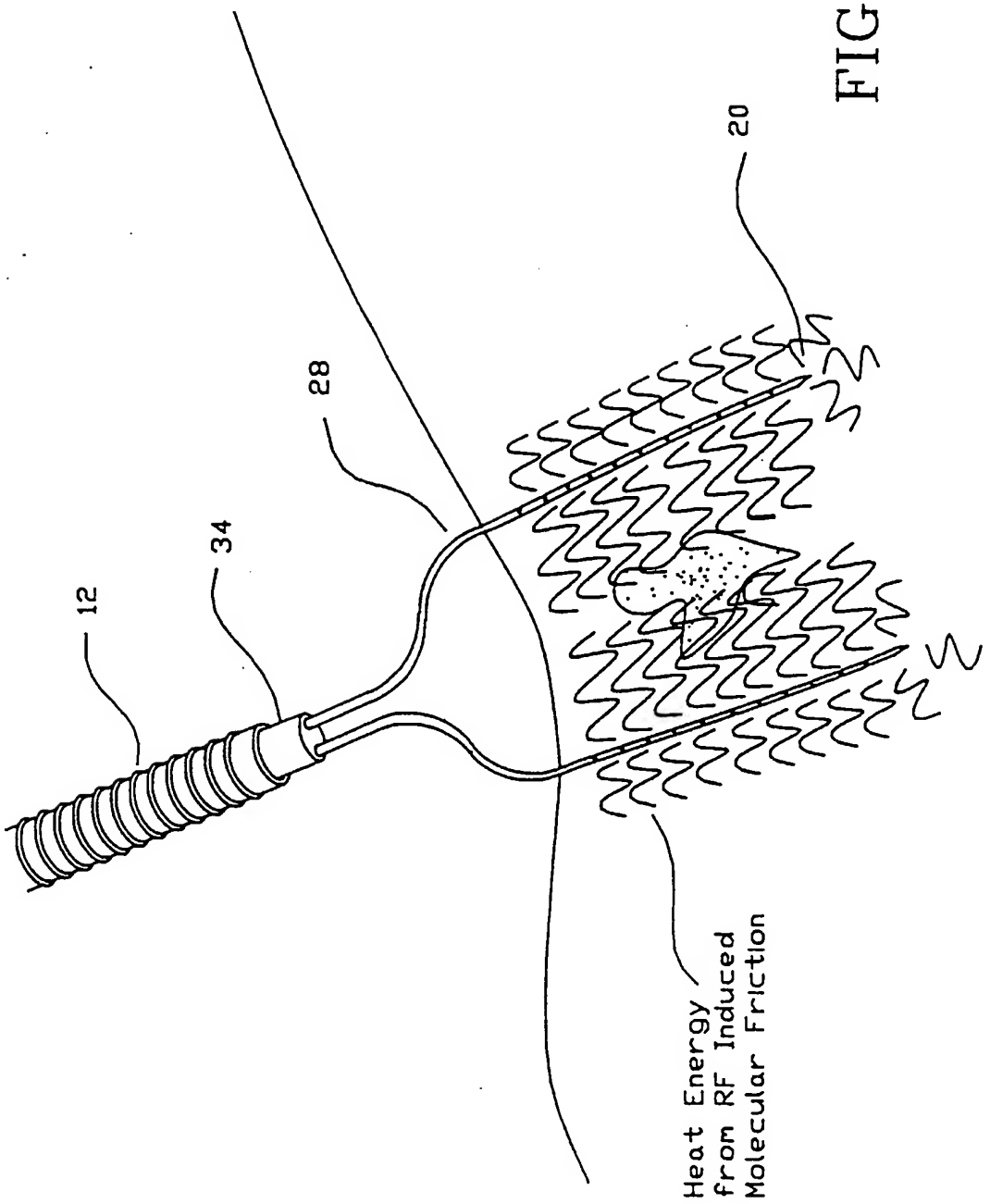


FIG. 16

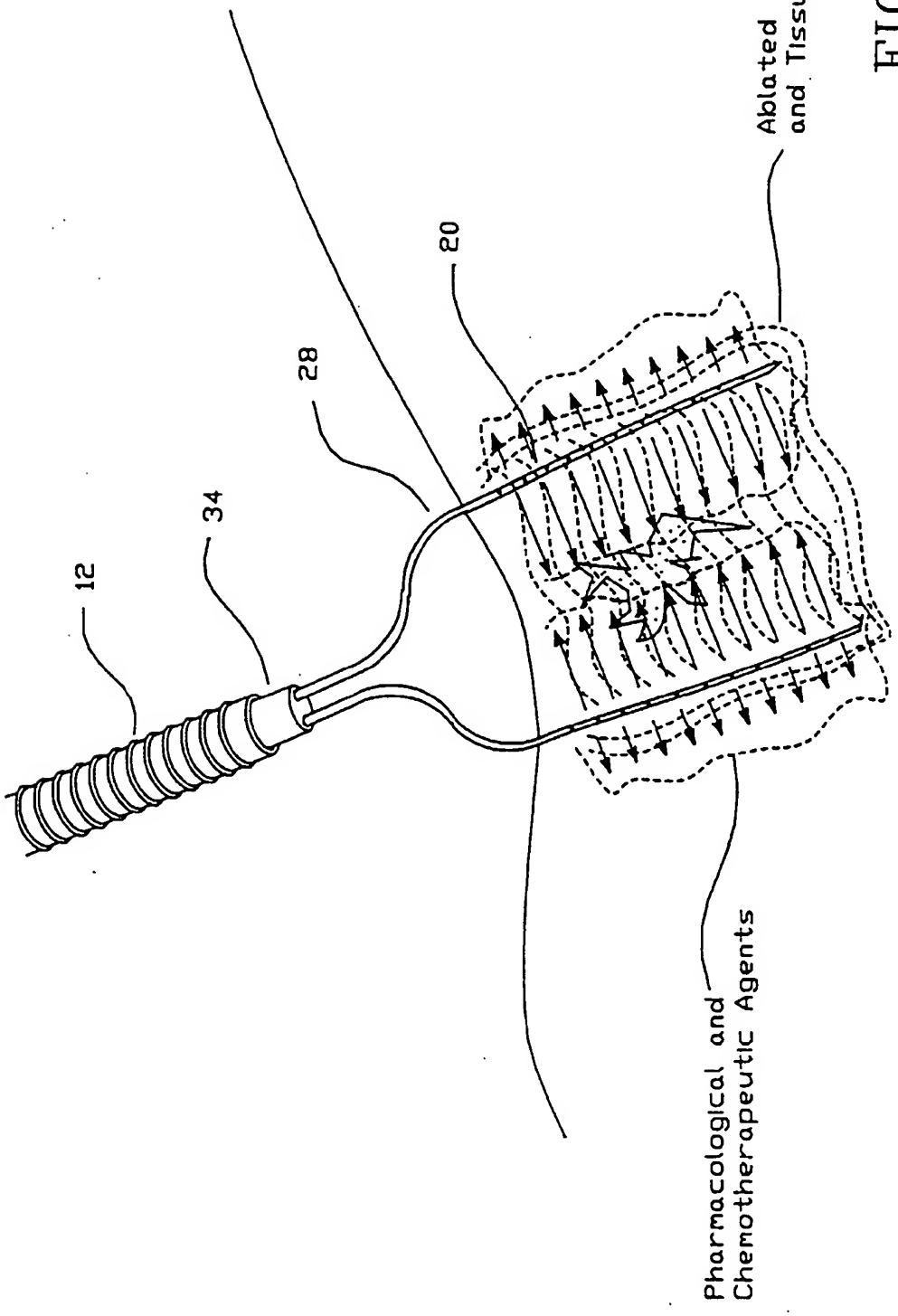

Ablated Tumor and Tissue
20
28
34
12
Pharmacological and Chemotherapeutic Agents

FIG. 17

FIG.18

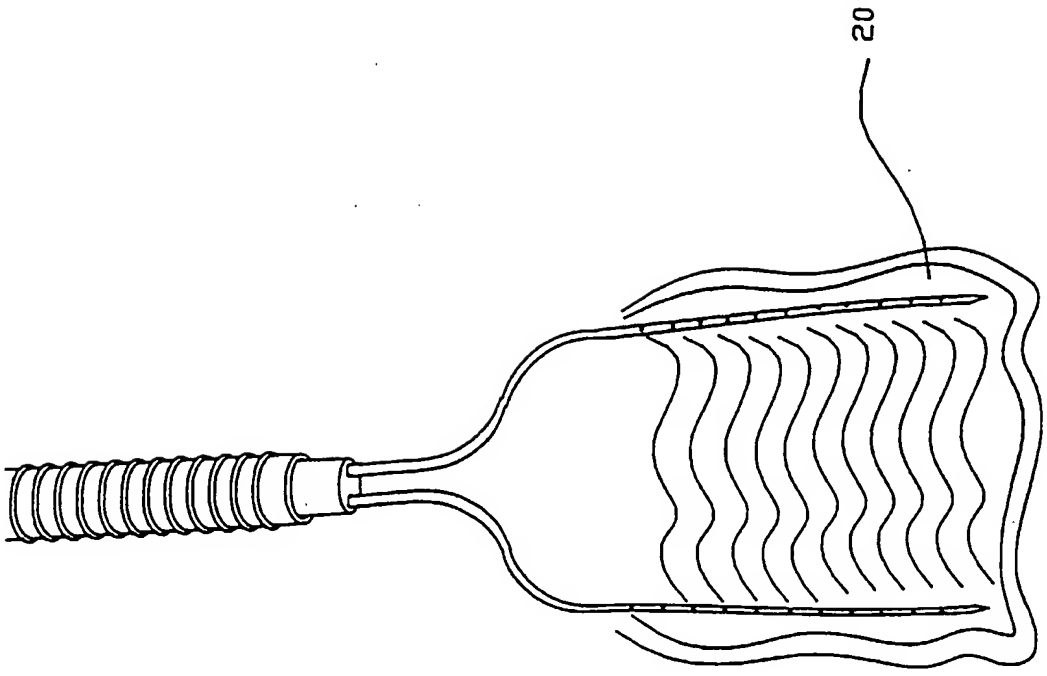
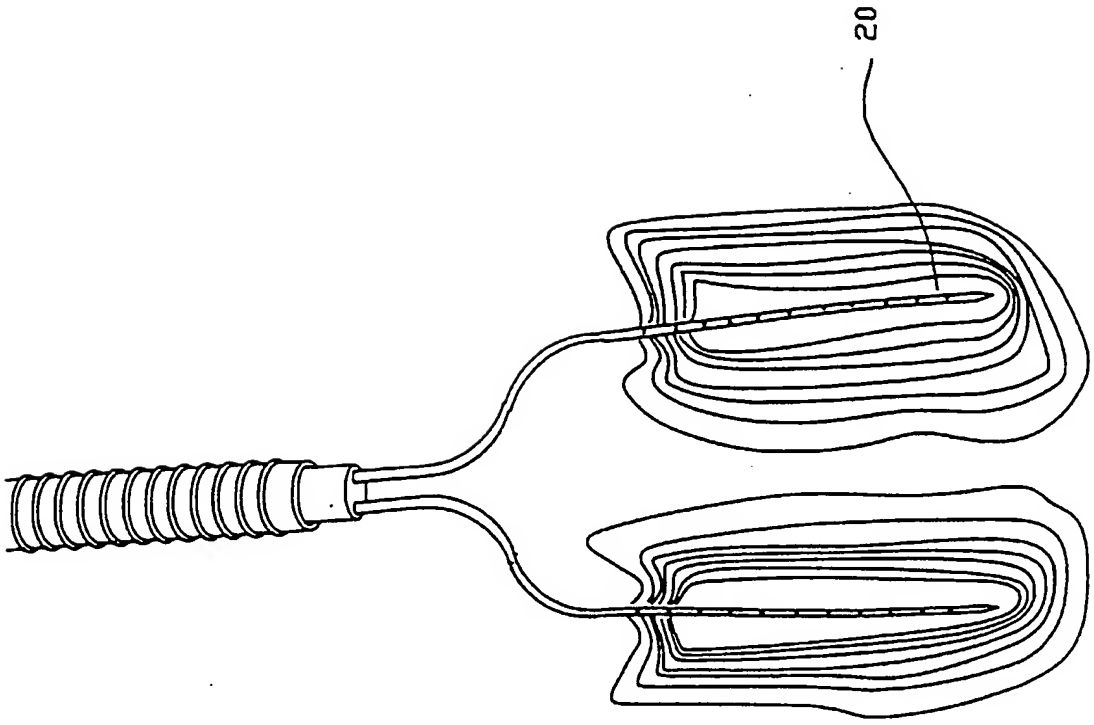


FIG.19



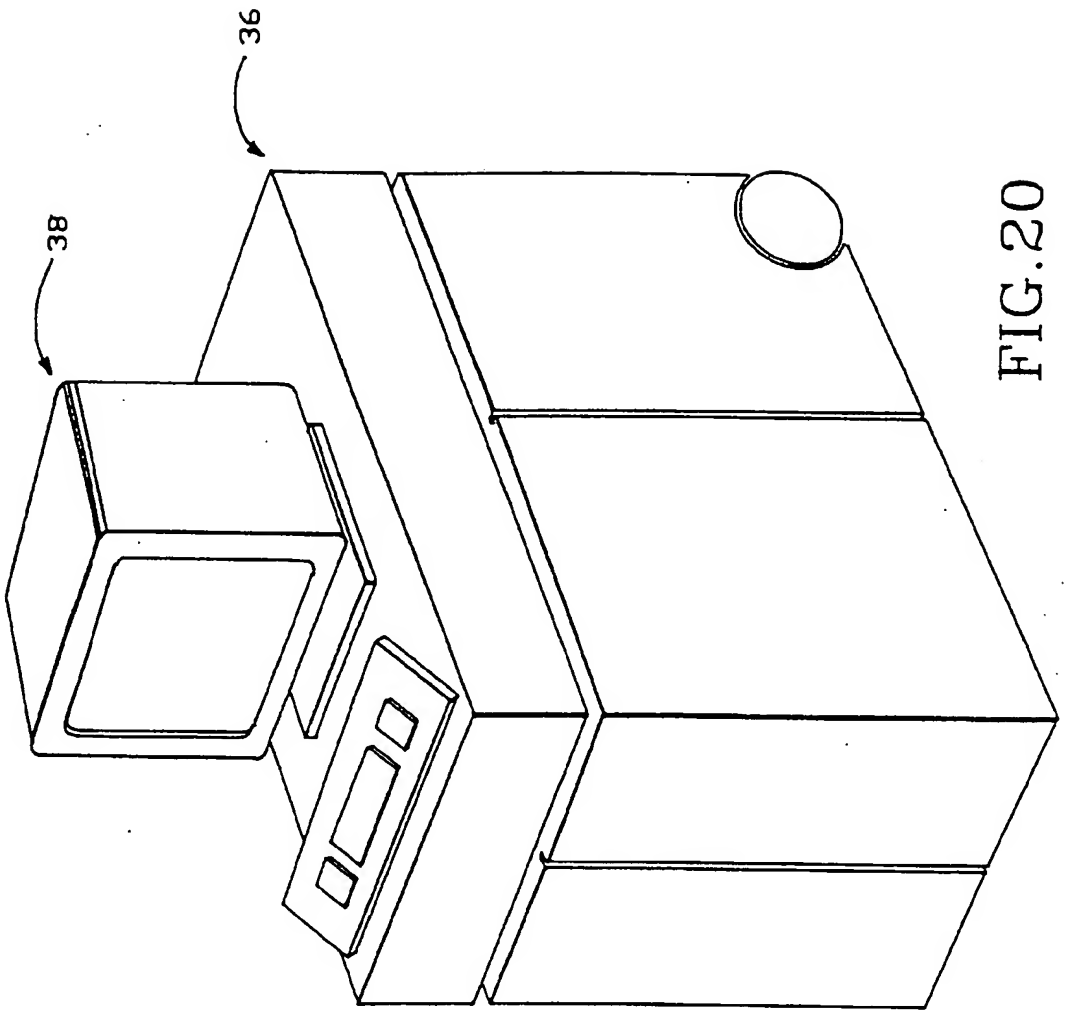


FIG.20

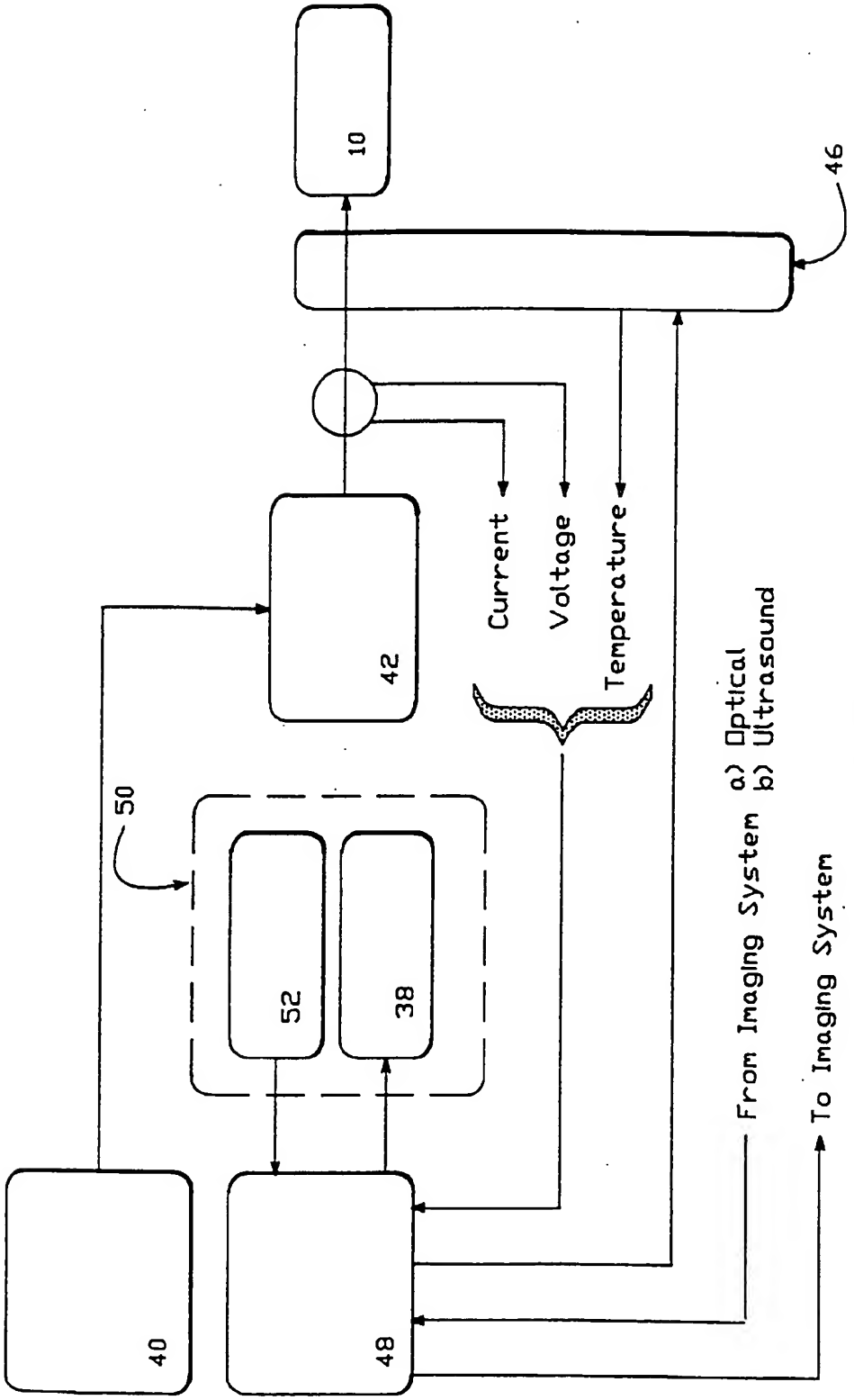

10
46
42
Current
Voltage
Temperature
50
52
38
40
48
From Imaging System a) Optical b) Ultrasound
To Imaging System

FIG.21

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 20 4115

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
D,X	DE 21 24 684 A (H. - G. STADELMAYR) 30 November 1972 * page 2, last paragraph - page 3, paragraph 1 *	1-14, 21-25	A61B17/39
D,X	WO 94 04220 A (VIDAMED) 3 March 1994 * page 11, line 31 - page 12, line 25 * * page 16, line 24 - line 35 * * page 17, paragraph 3 * * page 23, line 30 - page 24, paragraph 1 * * claims 3,10; figures 4,7,14 *	1-11, 15-21,25	
A	FR 2 283 701 A (FISCHER) 2 April 1976 * page 4, line 7 - line 15; figures 2,3 *	1,12	
A	US 5 259 394 A (BENS) 9 November 1993 * abstract; figures 1,2 *	1,12	
D,A	DE 89 09 492 U (UECKMANN) 8 February 1990 * page 2; figure 1 *	1	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	US 5 083 565 A (PARINS) 28 January 1992 * column 3, line 7 - line 24 * * column 3, line 37 - line 66 * * column 4, line 14 - line 29; figure 1 *	1	A61B
A	US 3 858 586 A (LESSEN) 7 January 1975 * column 5, line 62 - column 6, line 26 *	1	
A	DE 41 00 422 A (WOLF) 16 July 1992 * claim 1; figures 1,5 *	1	
A	EP 0 472 368 A (MED INSTITUTE) 26 February 1992 * abstract; figure 1 *	1	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	8 February 1999	Gérard, B

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 20 4115

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	DE 10 07 960 B (WOLF) * column 3, line 22 - line 25; figure 7 *	3	
A	US 4 026 301 A (FRIEDMAN ET AL.) 31 May 1977 * column 5, line 14 - column 6, line 59; figures 2-8 *	7-9	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	8 February 1999	Gérard, B

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98 20 4115

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

08-02-1999

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 2124684 A	30-11-1972	NONE	
WO 9404220 A	03-03-1994	US 5370675 A	06-12-1994
		AT 132046 T	15-01-1996
		AU 671405 B	22-08-1996
		AU 2047595 A	10-08-1995
		AU 657235 B	02-03-1995
		AU 4999893 A	15-03-1994
		CA 2121032 A,C	03-03-1994
		CA 2226484 A	03-03-1994
		DE 4305663 A	17-02-1994
		DE 69301143 D	08-02-1996
		EP 0611314 A	24-08-1994
		EP 0629382 A	21-12-1994
		EP 0893101 A	27-01-1999
		ES 2084510 T	01-05-1996
		FI 950584 A	04-04-1995
		FR 2694700 A	18-02-1994
		GB 2269538 A,B	16-02-1994
		IL 104647 A	31-12-1995
		JP 7503645 T	20-04-1995
		MX 9304905 A	29-04-1994
		NZ 255687 A	20-12-1994
		US 5385544 A	31-01-1995
		US 5421819 A	06-06-1995
		US 5435805 A	25-07-1995
		US 5409453 A	25-04-1995
		US 5470308 A	28-11-1995
		US 5366490 A	22-11-1994
		US 5556377 A	17-09-1996
		US 5720718 A	24-02-1998
		US 5542915 A	06-08-1996
		US 5470309 A	28-11-1995
		US 5554110 A	10-09-1996
		US 5549644 A	27-08-1996
		US 5484400 A	16-01-1996
		US 5630794 A	20-05-1997
		US 5514131 A	07-05-1996
		US 5672153 A	30-09-1997
		US 5720719 A	24-02-1998
		US 5531676 A	02-07-1996
		US 5536240 A	16-07-1996
		US 5542916 A	06-08-1996
		US 5599294 A	04-02-1997
		US 5540655 A	30-07-1996
		US 5667488 A	16-09-1997

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98 20 4115

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

08-02-1999

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9404220 A		US 5531677 A	02-07-1996
		US 5582589 A	10-12-1996
		US 5591125 A	07-01-1997
		US 5749846 A	12-05-1998
		US 5599295 A	04-02-1997
FR 2283701 A	02-04-1976	DE 2442605 A	25-03-1976
		BR 7505629 A	03-08-1976
		CH 587664 A	13-05-1977
		JP 51076888 A	03-07-1976
		US 4003380 A	18-01-1977
US 5259394 A	09-11-1993	FR 2671010 A	03-07-1992
		DE 69107045 D	09-03-1995
		DE 69107045 T	08-06-1995
		EP 0493221 A	01-07-1992
DE 8909492 U	08-02-1990	DE 3905734 A	30-08-1990
US 5083565 A	28-01-1992	NONE	
US 3858586 A	07-01-1975	NONE	
DE 4100422 A	16-07-1992	NONE	
EP 472368 A	26-02-1992	US 5100423 A	31-03-1992
		AT 124231 T	15-07-1995
		AU 643552 B	18-11-1993
		AU 8267591 A	27-02-1992
		CA 2049146 A	22-02-1992
		DE 69110794 D	03-08-1995
		DE 69110794 T	07-12-1995
		ES 2073687 T	16-08-1995
		JP 5137729 A	01-06-1993
DE 1007960 B		NONE	
US 4026301 A	31-05-1977	AU 514777 B	26-02-1981
		AU 3730978 A	07-09-1978
		AU 8729375 A	09-06-1977
		CA 1067962 A	11-12-1979
		CA 1081792 A	15-07-1980
		CA 1081793 A	15-07-1980
		DE 2617240 A	04-11-1976
		DE 2660864 C	13-06-1985
		FR 2319385 A	25-02-1977

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98 20 4115

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

08-02-1999

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4026301 A		GB 1552605 A	19-09-1979
		GB 1552606 A	19-09-1979
		GB 1552604 A	19-09-1979
		JP 1071855 C	30-11-1981
		JP 51128861 A	10-11-1976
		JP 56015263 B	09-04-1981
		NL 7601110 A,B,	25-10-1976
		SE 420161 B	21-09-1981
		SE 7514440 A	22-10-1976
		SE 440452 B	05-08-1985
		SE 7903485 A	20-04-1979

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82